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Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility

Office of Nuclear Material Safety and Safeguards
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U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

ABSTRACT

The Standard Review Plan (SRP) (NUREG-1520) provides guidance to the staff reviewers in the Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate fuel cycle facilities. The SRP ensures the quality, uniformity, stability, and predictability of the staff reviews. It presents a defined basis from which to evaluate proposed changes in the scope and requirements of the staff reviews. The SRP makes information about licensing acceptance criteria widely available to interested members of the public and the regulated industry. Each SRP section addresses the responsibilities of persons performing the review, the matters that are reviewed, the Commission's regulations pertinent to specific technical matters, the acceptance criteria used by the staff, how the review is accomplished, and the conclusions that are appropriate to summarize the review.

An integrated safety analysis (ISA), required by a revised 10 CFR Part 70, is produced by an applicant for a new, renewed, or revised license under Part 70. An ISA summary and other ISA documentation become fundamental in the NRC staff's review process, and the NRC staff's expectations for this work is described fully in this SRP. The work that is recorded in the applicant's ISA and ISA summary informs the applicant and the NRC staff of the risks inherent in the plant design and operation, and will provide the basis for the application of the NRC acceptance criteria presented in this SRP.

(Note: Existing criteria for the review of the safeguards sections of license applications may be incorporated in this SRP at a later date. These criteria were developed earlier and are published in NUREGs 1280 and 1365.)

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STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

CONTENTS

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

INTRODUCTION

The *Standard Review Plan for the Review of a License Application for a Fuel Cycle Facility* provides U.S. Nuclear Regulatory Commission (NRC) guidance for the review and evaluation of health, safety, and environmental protection in applications for licenses to possess and use special nuclear material (SNM) to produce nuclear reactor fuel. The guidance is also applicable to the review and evaluation of proposed amendments and license renewal applications. Specific filing requirements for license applications, and for issuance of such licenses, are in 10 CFR 70, "Domestic Licensing of Special Nuclear Material."

The principal purpose of the Standard Review Plan (SRP) is to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate proposed changes in the scope, level of detail, and acceptance criteria of reviews. The SRP also will be used as the basis for the review of requests by licensees for changes in their licenses. Thus, the SRP, at any point in time, provides the basis for the review of proposed new or renewal applications, and amendments to existing licenses, as well as modifications to the SRP resulting from new NRC requirements and licensee initiatives.

Another important purpose of the SRP is to make information about regulatory reviews widely available and to improve communication and understanding of the staff review process. Because the SRP describes the scope, level of detail, and acceptance criteria for reviewers, it serves as regulatory guidance for applicants who need to determine what information should be presented in a license application.

It is important to note that this SRP:
1) is a guidance document,
2) is for use during the review of license applications, license renewal applications, and amendment applications,
3) and does not prevent licensees or applicants from suggesting alternate means of demonstrating compliance.

The responsibility of the staff in the review of a license application, renewal application, or license amendment for a fuel cycle facility is to determine that there is reasonable assurance that the facility can and will be operated in a manner that will not be inimical to the common defense and security, and will provide adequate protection of the health and safety of workers and the public, and the environment. To carry out this responsibility, the staff evaluates information provided by an applicant and through independent assessments determines that the applicant has demonstrated an adequate safety program that is in accordance with regulatory requirements. To facilitate carrying out this responsibility, the SRP clearly states and identifies those standards, criteria, and bases that the staff will use in reaching licensing decisions.

NRC requirements in 10 CFR 70.61 require that an applicant submit a complete description of the safety program for the possession and use of SNM to show how compliance with the applicable requirements will be accomplished. The Safety Program Description must be sufficiently detailed to permit the staff to obtain reasonable assurance that the facility is designed and will be operated without undue risk to the health and safety of workers or the public. Prior to submission of the program description, an applicant should have analyzed the facility in sufficient detail to conclude that it is designed and can be operated safely. The Safety Program Description is the principal document with which the applicant provides the information needed by staff to develop the basis for conclusion. When reviewed and approved by the staff, and incorporated in the NRC license by reference, the Safety Program Description, in its entirety and in its parts, is considered a binding commitment of the applicant regarding the design and operation of the licensed facility. The Safety Program Description is the safety basis on which the license is issued, and may not be changed except under circumstances defined in 10 CFR Part 70.

The requirements in 10 CFR 70 specify, in general terms, the information to be supplied in a Safety Program Description. The specific information to be submitted by an applicant and evaluated by staff is identified in this SRP. Prospective applicants should study the topic areas treated in this document (generally, chapter headings) and the subsections within each topic area, specifically the subsections headed "Areas of Review" and "Acceptance Criteria." A license application should contain a Safety Program Description that addresses all the topics in the Table of Contents of this SRP, in the same order as presented in this document. The appendix provides additional guidance on the format of applications.

In this SRP, information is provided to assist the licensing staff and the applicant in understanding the underlying objective of the regulatory requirements, the relationships among NRC requirements, the licensing process, the major guidance documents NRC staff has prepared for licensing fuel cycle facilities, and the details of the staff review process set out in individual SRP sections. Analyses by the staff are intended to provide regulatory confirmation of reasonable assurance of safe design and operation. A staff determination of reasonable assurance leads to a decision to issue or renew a license or to approve an amendment. In the case of a staff determination of inadequate description or commitments, the staff will inform the applicant of what is needed and the basis upon which the determination was made.

The "Acceptance Criteria" delineated in this SRP are intended to communicate the underlying objectives but not to represent the only means of satisfying that objective. An applicant should tailor its safety program to the features of its particular facility. If approaches different from the SRP are chosen, the applicant should identify in its license application the portions of its application that differ from the design approaches and acceptance criteria of the SRP and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations. The staff retains the responsibility to make an independent determination of the adequacy of what is proposed.

The major topics addressed within the Safety Program Description of a facility license application are addressed in separate SRP sections; each of those sections, or chapters, includes subsections described below.

The applicant's ISA is the central focus for the selection of design and operational safety measures and the management control systems that assure the availability and reliability of those measures. The ISA should provide a comprehensive evaluation and presentation, useful to both the applicant and the NRC, of the distribution of risk among the many activities ongoing at a fuel cycle facility. The NRC expects to be able to use the ISA findings and conclusions to focus its resources on the dominant risks of facility design and operation and the safety controls and assurances necessary to ensure that those controls remain available and reliable. Accordingly, staff reviewers will conduct a coordinated review of the ISA and will focus on the information contained in the ISA summary applicable to each of the technical areas treated in the chapters of the SRP, although review of other ISA documentation may also be necessary. The acceptance criteria in each of the SRP chapters are the criteria that apply to the dominant risks of operation. The applicant has the opportunity to justify lesser criteria for those design and operational features that can be shown to represent lesser risk than the accident or failure sequences that pose the dominant risks.

While recognizing the fundamental importance of the ISA to understanding the risk at a facility, certain SRP chapters are less dependent on ISA outcomes than others. The chapters concerning radiation safety, environmental protection, emergency management, and decommissioning, for example, contain acceptance criteria that are set primarily by current regulations that have not been changed in issuing the revision to 10 CFR Part 70. Finally, for new facilities (that have not already been designed, built, licensed and operated), certain baseline design criteria have been specified in 10 CFR 70.64. These criteria apply prior to the NRC approval of an ISA for the complete, final design which may indicate that reduced levels of assurance are acceptable in certain instances. The acceptance criteria in the SRP chapters implement the baseline design criteria in 10 CFR 70.64(a). A more detailed description of the application of these criteria is given in the discussion of "Section 4. *Acceptance Criteria*" below.

Section 1. PURPOSE OF REVIEW

This section is a brief statement of the purpose for and objectives of reviewing the subject areas. It emphasizes the staff's evaluation of the ways the applicant will achieve identified performance objectives and ensures through the review that the applicant has used a multi-disciplinary, systems-oriented approach to establishing designs, controls, and procedures within individual technical areas.

Section 2. RESPONSIBILITY FOR REVIEW

This section identifies the organization and individuals by function, within NRC, responsible for evaluating the subject or functional area covered by the SRP. If reviewers with expertise in other areas are to participate in the evaluation, they are identified by function. In general, the Licensing Project Manager has responsibility for the total review product, a safety evaluation report for an application. However, an identified technical specialist will have primary responsibility for a particular review topic, usually an SRP chapter. One or more specialists may have supporting responsibility. In most situations the review is performed by a team of specialist reviewers including the lead reviewer for the ISA and the project manager. Although they individually perform their review tasks, the reviews are extensively coordinated and integrated to ensure consistency in approach and to ensure risk-informed reviews. The project

manager oversees and directs the coordination of the reviewers. The reviewers' immediate line management has the responsibility to ensure that an adequate review is performed by qualified reviewers.

Section 3. AREAS OF REVIEW

This section describes the topics, functions, systems, components, analyses, data, or other information that should be reviewed as part of that particular subject area of the license application. Because the section identifies information to be reviewed in evaluating the adequacy of the application, it identifies the acceptable content of an applicant's submittal in the areas discussed. The areas of review identified in this section obviate the need for a separate Standard Format and Content Guide.

The topics identified in this section also set the content of the next two sections of the SRP. Both Section 4, "Acceptance Criteria," and Section 5, "Review Procedures," should address, in the same order, the topics set forth in this section as areas to be reviewed. This section also identifies the information needed or the review expected from other NRC individuals to permit the individual charged with primary review responsibility to complete the review.

Section 4. ACCEPTANCE CRITERIA

This section contains a statement of the applicable NRC criteria based on regulatory requirements, and the bases for determining the acceptability of the applicant's commitments relative to the design, programs, or functions within the scope of the particular SRP section. Technical bases consist of specific criteria such as NRC regulations, regulatory guides, NUREG reports, industry codes and standards, and branch technical positions. To the extent practicable, the acceptance criteria will identify, as objectively or quantitatively as is feasible, specific requirements and other technical bases that are to be satisfied. The acceptance criteria (including branch technical positions or other information) present positions and approaches that are acceptable to the staff. They are not considered the only acceptable positions or approaches. Others may be proposed by an applicant.

It is NRC's intent that the SRP presents acceptance criteria for each technical function area (e.g., nuclear criticality safety, fire safety, radiation safety), and for the management control systems (e.g., quality assurance, maintenance, audits and assessments), that allow an applicant to provide a level of protection commensurate with the accident risk inherent in the process activities proposed. For example, at process stations (or for an entire process or sub-process) for which the inherent risk to workers, the public, or the environment is demonstrably small, the applicant needs to provide only those design and operating controls which assure that small risk. The key elements in the regulatory transaction involving presentation by an applicant, and review and approval by the NRC, are an adequate demonstration of acceptable control of risk by the applicant, which then supports a competent and informed review by NRC staff. The starting point for the applicant's demonstration of acceptable control of risk is the ISA.

The applicant's ISA is the primary supporting rationale for the safety level of design and operational features. There are, however, design and operational features and management controls that may be required independent of the ISA. This is to meet the requirements of 10

CFR 70.64 for new facilities or new processes at existing facilities, or, for all facilities, other NRC requirements such as 10 CFR Parts 20 and 51. The level of detail presented in the ISA summary submitted to NRC and in other parts of the application represents the safety basis committed to by the applicant, and is the basis which is subject to the provisions of 10 CFR 70.72 regarding changes that a licensee may make to the facility without prior NRC approval.

NRC will find an application acceptable if an applicant commits to the design features and management measures defined by the acceptance criteria within this SRP. The criteria in this SRP represent the design features or management measures that support an NRC finding of reasonable assurance of adequate protection, independent of any ISA findings or conclusions that could lead to NRC approval of reduced levels of assurance for certain design features or management measures where the associated risk does not warrant the same high level of assurance.

An applicant for license renewal or an amendment for an existing facility responding to the requirements of 10 CFR Part 70 may propose structures, systems, and components (SSC) or management measures that meet less stringent acceptance criteria than described in the SRP based on supporting analyses from the applicant's ISA. The ISA may be used to justify a reduced level of assurance for particular items relied on for safety, that are associated with lesser risk accident sequences, as defined by the applicant's analysis of likelihood and consequences pursuant to 10 CFR 70.61. The criteria shown in this SRP apply to those SSC and management measures that are involved in the higher risk accident sequences as defined in §70.61.

For proposed new facilities or amendments for new processes proposed at existing facilities, the acceptance criteria described in the SRP apply for design purposes and should be addressed in the applicant's licensing submittal for all SSC and management measures, in accordance with 10 CFR 70.64. During NRC review of the ISA summary, license application contents, and other ISA documentation as needed, the applicant may justify reduced criteria for some SSC and management measures based on the ISA findings or conclusions.

Applicants should recognize that substantial time and effort on the part of the staff have gone into the development of the acceptance criteria and that a significant amount of time and effort may be required to review and accept proposals that depart from the standard applications described in the SRP. Thus, applicants resolving safety issues or safety-related design areas in ways other than those described in the SRP should plan for longer review times and more extensive questioning in these areas.

Section 5. REVIEW PROCEDURES

This section describes how the review will be performed. It generally describes procedures that the reviewer should follow to achieve an acceptable scope and depth of review and to obtain reasonable assurance that the applicant has provided appropriate commitments to ensure that it will operate the facility safely. This includes identifying licensee commitments to verify and could include directing the reviewer to coordinate with others having review responsibilities for other portions of the application than that assigned to the reviewer. This

section should provide whatever procedural guidance is necessary to evaluate the applicant's level of achievement of the acceptance criteria.

Section 6. EVALUATION FINDINGS

This section presents the type of positive conclusion that is sought for the particular review area to support a decision to grant a license or amendment. The review must be adequate to permit the reviewer to support this conclusion. For each section, a conclusion of this type will be included in the staff's Safety Evaluation Report (SER) in which the staff publishes the results of its review. The SER will also contain a description of the review, including aspects of the review that received special emphasis; matters that were modified by the applicant during the review; matters that require additional information or will be resolved in the future; aspects where the plant's design or the applicant's proposals deviate from the criteria in the SRP; and the bases for any deviations from the SRP or proposed exemptions from the regulations. Staff reviews may be documented in the form of draft SERs that identify open issues requiring resolution before the staff can make a positive finding in favor of the license issuance or amendment.

Section 7. REFERENCES

This section lists references that should be consulted in the review process. However, they may not always be relevant to the review, depending on the action and approaches proposed by the applicant.

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ACRONYMS AND ABBREVIATIONS

AEGL	Acute Exposure Guideline Level
ALARA	As Low As Reasonably Achievable
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BDC	Baseline Design Criteria
CAM	Continuous Air Monitor
CFR	Code of Federal Regulations
CM	Configuration Management
EA	Environmental Assessment
EIS	Environmental Impact Statement
ERPG	Emergency Response Planning Guidelines
FCLB	Fuel Cycle Licensing Branch
FHA	Fire Hazards Analysis
FONSI	Finding of No Significant Impact
HS&E	Health, Safety and Environmental
ISA	Integrated Safety Assessment
ISO	International Organization for Standardization
LIB	Licensing and International Safeguards Branch
MOU	Memorandum of Understanding
NCS	Nuclear Criticality Safety
NEPA	National Environmental Policy Act
NFPA	National Fire Protection Association
NRC	Nuclear Regulatory Commission

OSHA	Occupational Safety and Health Administration
RWP	Radiation Work Permits
SECY	Office of the Secretary of the Commission
SER	Safety Evaluation Report
SNM	Special Nuclear Material
TWA	Time-weighted Average
QA	Quality Assurance

GLOSSARY

The following terms are defined here by the staff for the purposes of this SRP. Many of the terms are taken from 10 CFR70.4. The definitions from this CFR section have not been changed in the list below, but are repeated for convenience. Terms listed in this glossary represent the definition of the word in any chapter of this SRP. Words for which the definitions change between chapters are listed in the individual chapters.

Active-engineered controls	Controls that use active sensors to determine values of Controlled Parameters and automatically provide a response. Operation of these controls require no human intervention.
Accident sequence	In general, an unintended sequence of events or process failures that would result in adverse consequences. In the context of this SRP, an unintended sequence of events which results in environmental contamination, a radiation exposure, a release of radioactive material, an inadvertent nuclear criticality, or an exposure to hazardous chemicals, provided the chemicals are produced from licensed radioactive material; or if the accident has the potential to jeopardize the safety of regulated activities. The term “accident” may be used interchangeably with accident sequence.
Acute	As used in section 70.61of this Part means a single radiation dose or chemical exposure event or multiple radiation dose or chemical exposure events occurring within a short time (24 hours or less).
Augmented-administrative controls	Controls that use warning device(s) to notify humans that intervention is necessary to implement the controls. Operation of these controls require human intervention for implementation
Available and reliable to perform their function when needed	As used in Subpart H of the Part means that, based upon the analyzed, credible conditions in the integrated safety analysis, items relied on for safety will perform their intended safety function and management measures will be implemented that ensure continuous compliance with the performance requirements of §70.61 of this Part, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and measures.
Baseline Design Criteria	A set of criteria specifying design features and assurance measures that are required and acceptable under certain conditions for new processes or facilities specified in 10 CFR 70.64. These criteria are, in general, the acceptance criteria

	applicable to safety design described in the chapters of this SRP.
Configuration management (CM)	Ensuring, as part of the safety program, oversight and control of all design information, safety information, and modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed.
Control	A system or device intended to regulate a device or process.
Controlled Parameter	A measurable parameter for which the value is maintained within a specified range by specific controls to ensure the safety of an operation.
Consequence	Any result of interest caused by an event or sequence of events. In this context, adverse consequences refers to the adverse health or safety effects on workers or the public, and to adverse environmental impacts of accidents.
Consequence of concern	Adverse radiological, chemical, or environmental effects exceeding any of the levels specified in 10 CFR 70.61.
Credible event	An initiating (or secondary) event that is not an incredible event (e.g., an event with a likelihood of occurrence greater than one in a million in any year). Any accident sequence identified in the ISA as initiated by a credible event must have its consequences assessed, and controls applied so as to comply with 10 CFR 70.61.
Critical mass of special nuclear material (SNM)	Special nuclear material in a quantity exceeding 700 grams of contained uranium-235; 520 grams of uranium-233; 450 grams of plutonium; 1500 grams of contained uranium-235, if no uranium enriched to more than 4 percent by weight of uranium-235; 450 grams of any combination thereof; or one-half such quantities if massive moderators or reflectors made of graphite, heavy water, or beryllium may be present.
Deviation from safe operating conditions	A parameter that is controlled to ensure adequate protection is outside its established safety limits, or that an item relied on for safety has been lost or has been degraded so that it cannot perform its intended function.
Double contingency	A process design that incorporates sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Double contingency principle	A licensed processes should, in general, incorporate sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.
Double contingency protection	A licensed process possesses double contingency protection if it has incorporated the double contingency principle. Double contingency protection is the standard; exceptions should be made only when it is not practicable and then redundancy and diversity of controls is expected to be present in the process.
Event	An occurrence; a change of conditions from a prior state.
External event	An event for which the likelihood cannot be altered by changes to the regulated facility or its operation. This would include all natural phenomena events plus airplane crashes, explosions, toxic releases, fires, etc. occurring near or on the plant site that cannot be controlled by actions of plant personnel.
Hazardous chemicals produced from licensed materials	Substances having licensed material as precursor compound(s) or substances that physically or chemically interact with licensed materials; that are toxic, explosive, flammable, corrosive, or reactive to the extent that they can endanger life or health if not adequately controlled. These include substances commingled with licensed material, and include substances such as hydrogen fluoride that is produced by the reaction of uranium hexafluoride and water, but do not include substances prior to process addition to licensed material or after process separation from licensed material.
Integrated safety analysis (ISA)	A systematic analysis to identify plant and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the site, structures, systems, equipment, components, and activities of personnel that are relied on for safety. As used here, *integrated* means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this Part, the focus of the integrated safety analysis is limited to the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC licensed radioactive material.
Integrated safety analysis summary	The document submitted in conjunction with the license

	application, license amendment application, or license renewal renewal application that provides a synopsis of the results of the information the integrated safety information specified in §70.65(b)
Items relied on for safety	Structures, systems, equipment, components, and activities of personnel that are relied on to prevent potential accidents at a facility that could exceed the performance requirements in §70.61 or to mitigate their potential consequences. However, the does not limit the licensee from identifying additional structures, systems, equipment, components, and activities of personnel(i.e, beyond those in the minimum set necessary for compliance with the performance requirements) as items relied on for safety.
Management measures	The functions performed by the licensee, generally on a continuing basis, that are applied to items relied upon for safety, identified in the integrated safety analysis, to ensure they are available and reliable to perform their functions when needed. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, records management, and other quality assurance systems.
Mitigative control	A control intended to reduce the consequences of an accident sequence, not to prevent it entirely. When a mitigative control works as intended, the results of the sequence are called the mitigated consequences.
Natural phenomena event	Earthquakes, floods, tornadoes, tsunamis, hurricanes, and other events that occur in the natural environment and could adversely affect safety. Natural phenomena events, depending on their likelihood of occurrence, may be credible or incredible.
New processes at existing facilities	Systems-level or facility-level design changes to process equipment, process technology, facility layout, or types of licensed material possessed or used. This definition does not, generally, include component-level design changes or equipment replacement.
Passive-engineered Controls	Controls that use only fixed design features to control a Controlled Parameter. Operation of these controls require no human intervention.

Preliminary process hazards analysis (PHA)	An analysis undertaken during the early design or development phases of a process to identify the principal hazards and to enable them to be eliminated, minimized or controlled with minimal cost or disruption. The analysis also assists in identification and optimization of potential corrective, mitigative or preventive safety controls and management measures.
Preventive control	A control intended to prevent an accident entirely, i.e., to prevent any of the types of radiological or chemical consequences in 10 CFR 70.61 of any magnitude.
Safety control	A system, device, or procedure intended to regulate a device, process, or human activity, so as to maintain a safe state. Effectively synonymous with “item relied on for safety”. In the context of this SRP, use of the unmodified term “control” normally means safety control. Other controls will be referred to as “process controls”. The function of safety controls is the avoidance of consequences of concern defined in 10 CFR Part 70.61. Controls may be active or passive engineered controls or administrative (procedural) controls. Controls may be preventive or mitigative. A process control may or may not be “an item relied on for safety” depending on whether the control of the process is required to assure safety.
Simple-administrative controls	Controls that requires only human intervention for implementation
Unacceptable performance deficiencies	Deficiencies in the items relied on for safety or the measures used to assure the items are available and reliable to perform their function when needed, that need to be corrected to ensure an adequate level of protection as defined in 10 CFR 70.61(b), (c), or (d).
Uncontrolled outcome	The sequence of events and consequences that result if no controls or barriers are available to prevent or mitigate an accident sequence. Thus the consequences of an uncontrolled outcome are, by definition, unmitigated. These consequences may also be referred to as uncontrolled consequences.
Unmitigated consequences	The consequences that result from an accident sequence when mitigative control fails or does not exist.

Worker	An individual whose assigned duties in the course of employment involve exposure to radiation and/or radioactive material from licensed and unlicenced sources of radiation (i.e., an individual who is subject to an occupational dose as in 20 CFR 20.1003).

1.1 FACILITY AND PROCESS DESCRIPTION

1.1.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the license application includes an overview of the facility layout and a summary description of the structures, systems, equipment, components, and actions of personnel (SSC) used in the processes that comprise the facility's operating objectives. This overview of the application will be used by all reviewers, NRC managers, and the general public to understand the purpose of the facility and its processes; a more detailed description of this information should be provided in appropriate sections of the ISA summary.

1.1.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: None

1.1.3 AREAS OF REVIEW

The staff should review the general facility description and process descriptions provided by the applicant, which should include (1) scaled drawings showing the locations of facility buildings and other major structures, hazardous materials storage areas, on-site roadways, railroad spurs or sidings, and major ingress and egress routes for the site, (2) a text index with titles that are descriptive of the purpose of each feature, (3) the interrelationships of the features, (4) the relationship of facility features to site features, and (5) the movement of personnel, materials, and equipment during facility operations. This information should be consistent with and summarize the information provided in the applicant's ISA summary in response to the acceptance criteria of this SRP, Section 3.4.3 "Acceptance Criteria", and should also be consistent with information reviewed under the Environmental Protection and Emergency Management chapters of this SRP.

1.1.4 ACCEPTANCE CRITERIA

1.1.4.1 Regulatory Requirements

The regulation applicable to the areas of review in this SRP is 10 CFR 70.22, "Contents of Applications", §70.60, “Applicability”, and §70.61, “Safety Performance Requirements”.

1.1.4.2 Regulatory Guidance

There are no regulatory guides that apply to a general facility description for a fuel cycle facility.

1.1.4.3 Acceptance Criteria

The reviewer will determine that the applicant’s presentations with respect to this section of the SRP are acceptable if the following criteria are met:

1. The application presents the facility and process description at a level of detail appropriate for general familiarization and understanding of the proposed facility and processes.

2. The application presents a summary of the facility information presented in the application in response to the guidance described in Section 3.5, Item 2 of this SRP. This includes descriptions of the overall plant layout on scaled drawings, including site geographical features, and plant structural features such as buildings, towers, and tanks and transportation right of ways. The relationship of specific facility features to the major processes that will be ongoing at the facility is described.

3. The major chemical or mechanical processes involving SNM to be licensed are described in summary form, based in part on information presented in the application in response to the guidance described in Section 3.5, Item 3 of this SRP. This description should include reference to the building locations of major components of the processes, brief descriptions of the process steps, the chemical forms of SNM in process, the maximum amounts of SNM in process in various building locations, and the types, amounts, and discharge points of waste materials discharged to the environment from the processes.

4. The general description of the facility and processes is consistent with, yet less detailed than, information presented in the applicant’s ISA summary.

1.1.5 REVIEW PROCEDURES

1.1.5.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the content of the application as required by 10 CFR Part 70 regarding facility and process design for fuel cycle facilities has been included, and that topics discussed in Section 1.1.3, "Areas of Review," have been included.

If significant deficiencies are identified in the application, the applicant should be requested to submit additional material before the start of the safety evaluation. The reviewer should then determine that the applicant has provided the information required. If necessary, a request for additional information should be prepared for issue to the applicant. With the complete submittal available, the reviewer should examine the summary data and determine acceptability by comparison with the acceptance criteria in section 1.1.4.3 above and information in the ISA summary.

1.1.5.2 Safety Evaluation

If the application is accepted for NRC review, the reviewer will proceed by comparing the application with the acceptance criteria. The material to be reviewed is informational in nature, and no technical analysis is required. The information to be reviewed is only used as background for the more detailed descriptions in later sections of the application. Therefore, the primary reviewer only confirms that the descriptive information presented is consistent with the information presented in the ISA summary.

1.1.6 EVALUATION FINDINGS

The staff's review verifies that sufficient information has been provided in the license application to satisfy the 10 CFR Part 70 requirements for this section and that the regulatory acceptance criteria in section 1.1.4.3 are appropriately satisfied. On the basis of this information, the staff concludes that this evaluation is complete. The reviewer writes material suitable for inclusion in the SER prepared for the entire application. The report includes a summary statement of what was reviewed and why the reviewer finds the submittal acceptable. The staff can document the review as follows:

The staff has reviewed the general facility description for [name of facility] according to the Standard Review Plan Section 1.1. The applicant has adequately described (1) the facility and processes so that the staff has an overall understanding of the relationships of the facility features and (2) the function of each feature. The applicant has cross-referenced its general description with the more detailed descriptions elsewhere in the application. The staff concludes that the applicant has complied with the general requirements of 10 CFR 70.22, "Contents of Applications", §70.60, “Applicability”, and with §70.61, “Safety Performance Requirements”, as applicable to this section.

1.1.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

1.2 INSTITUTIONAL INFORMATION

1.2.1 PURPOSE OF REVIEW

The purpose of this review is to establish that the license application includes adequate information identifying the applicant, the applicant's characteristics, and the proposed activity.

1.2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: Office of the General Counsel; Office of Administration/Division of Security

1.2.3 AREAS OF REVIEW

Information provided for review should include the identity and address of the applicant's facility and corporate headquarters; corporate information sufficient to show the relationship of the applicant's organization relative to other corporate entities; the existence and extent of foreign ownership or influence; financial information sufficient to indicate the resources available to the applicant to pursue the activities for which the license is sought; the site location as legally described in land records; a description of each proposed licensed activity in the form of requested authorized uses; the type of license being applied for; and the type, quantity, and form(s) of material(s) proposed to be licensed.

1.2.4 ACCEPTANCE CRITERIA

1.2.4.1 Regulatory Requirements

The regulations applicable to the areas of review in this SRP are 10 CFR 70.22, "Contents of applications", §70.23, "Requirements for the Approval of Applications", §70.61, "Performance Requirements", §70.65, "Additional Contents of Applications," 10 CFR 2.109 "Effect of Timely Renewal Application, " 10 CFR 70.33, "Renewal of Licenses," and 10 CFR 95, "Security Facility Approval and Safeguarding of National Security Information and Restricted Data."

1.2.4.2 Regulatory Guidance

There are no regulatory guides that apply to institutional information for a fuel cycle facility.

1.2.4.3 Regulatory Acceptance Criteria

The application is acceptable if the following criteria are met:

1. Corporate Identity

   The applicant has furnished its full name and address. The address of the fuel cycle facility is provided if it is different from that of the applicant. If the application is for renewal, the applicant identifies the number of the license to be renewed. A full description of the plant site location (State, county, and municipality) is given. The State where the applicant is incorporated or organized and the location of the principal office are indicated. If the applicant is a corporation or other entity, the names and citizenship of its principal officers are provided. The entity to be licensed is clearly described with respect to any higher level related corporate structure. The description clearly identifies and explains any proposed foreign ownership or control of activities, and shows that there is no foreign controlling interest. Primary ownership and relationships to other components of the same ownership are explicitly described. The presence and operations of any other company on the site to be licensed are fully described.

2. Financial Qualifications

   A description of financial qualifications demonstrates the applicant's current and continuing access to the financial resources necessary to engage in the proposed activity in accordance with §70.22(a)(8) and §70.23(a)(5).

3. Type, Quantity, and Form of Licensed Material

   The elemental name, maximum quantity, and specifications, including the chemical and physical form(s), of the special nuclear material the applicant proposes to acquire, deliver, receive, possess, produce, use, transfer or store are identified. For special nuclear material, the specifications include the isotopic content and amount of enrichment by weight percent. In addition, any trace impurities or contaminants, such as fission products or transuranics are characterized by identity and concentration. The applicant describes the amounts, if any, of Agreement State licensed radioactive material for the proposed facility. The proposed possession at the facility of any moderator or reflector with special characteristics, such as beryllium or graphite, is identified.

4. Authorized Uses

   Each activity or process in which special nuclear material is proposed to be acquired, delivered, received, possessed, produced, used, processed, transferred, or stored is described. The authorized uses are consistent with the Atomic Energy Act of 1954, et

seq. The description is consistent with more detailed process descriptions submitted as part of the ISA summary reviewed under Section 3.0 of this SRP.

If the application is for a renewal, the applicant states the period of time for which license renewal is requested, and why the renewal application should be considered timely in accordance with 10 CFR 70.

5. Special Exemptions or Special Authorizations

Specific requests for exemptions or authorizations of an unusual nature should be listed in this section and justified in the appropriate technical section of the application.

6. Security of Classified Information

If applicable, applicant has requested and received a facility security clearance in accordance with 10 CFR 95.

1.2.5 REVIEW PROCEDURES

1.2.5.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the content of the application has been included as required by 10 CFR Part 70 regarding institutional information for fuel cycle facilities and that the information discussed in Subsection 1.2.3, "Areas of Review," has been included.

If significant deficiencies are identified in the application, the applicant will be requested to submit additional material before the start of the safety evaluation.

1.2.5.2 Safety Evaluation

If the application is accepted for review, the reviewer conducts the review with respect to the acceptance criteria in section 1.2.4 above. The material to be reviewed is for the most part informational in nature, except for information on financial qualifications and foreign ownership and control, and detailed technical analysis is generally not required beyond the acceptance criterion. The reviewer requests review assistance, as needed, from the Division of Security and the Office of the General Counsel in the review of corporate and financial information. The material provided by the applicant should satisfy the acceptance criteria of section 1.2.4. above.

1.2.6 EVALUATION FINDINGS

The staff's review will verify that sufficient information has been provided in the license application to satisfy the regulations listed under section 1.2.4.1 above with respect to institutional information and that the information provided is consistent with the guidance of this

SRP. On the basis of this information, the staff will conclude that this evaluation is complete. The staff can document its review as follows:

The staff has reviewed the institutional information for [name of facility] according to Standard Review Plan Section 1.2. Based on the review, the NRC staff has determined that the applicant has adequately described and documented the corporate structure and financial information, and that the applicant is in compliance with those parts of 10 CFR 70.22 and 70.65 relating to other institutional information. In addition, the applicant has adequately described the types, forms, quantities, and proposed authorized uses of licensable materials to be permitted at this facility as follows:

Material	Form	Quantity	Authorized Use(s)

The applicant's proposed activities are consistent with the Atomic Energy Act. The applicant has provided all institutional information necessary to understand the ownership, financial qualifications, location, planned activities, and nuclear materials to be handled in connection with the requested license.

1.2.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

1.3 SITE DESCRIPTION

1.3.1 PURPOSE OF REVIEW

The purpose of this review is to determine that the information provided by an applicant adequately describes the geographic, demographic, meteorologic, hydrologic, geologic, and seismologic characteristics of the site and the surrounding area. The site description is a summary of the information used by the applicant in preparing the Environmental Report, Emergency Plan, and the ISA summary, which identify hazards, potential credible accidents, and the consequences of those accidents.

1.3.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: ISA Reviewer, Environmental Protection Reviewer, and Emergency Plan Reviewer

Supporting: Fuel Facility Inspection staff

1.3.3 AREAS OF REVIEW

The types of information NRC staff will review include the following (as appropriate for the facility being reviewed):

1. Site Geography

   a. Site location: state, county, municipality, topographic quadrangle (71/2 minute series).
   b. Major nearby highways.
   c. Nearby bodies of water.
   d. Any other significant geographic feature that may impact accident analysis within one mile of the site (e.g., ridges, valleys, specific geologic structures).

2. Demographics

   a. Latest census results for area of concern.
   b. Description, distance, and direction to nearby population centers.
   c. Description, distance, and direction to nearby public facilities (e.g., schools, hospitals, parks).

d. Description, distance, and direction to nearby industrial areas or facilities that may present potential hazards (including other nearby nuclear facilities).
e. Uses of land within one mile of the facility (i.e., residential, industrial, commercial, agricultural).
f. Uses of nearby bodies of water.

3. Meteorology

a. Primary wind directions and average wind speeds.
b. Annual amount and forms of precipitation. The design basis values for accident analysis of maximum snow or ice load, probable maximum precipitation.
c. Type, frequency, and magnitude of severe weather (e.g., lightning, tornado, hurricane). Design basis event descriptions for accident analysis.

4. Hydrology

a. Characteristics of nearby rivers, streams, and bodies of water as appropriate.
b. Depth to the water table; potentiometric surface map.
c. Groundwater flow direction and velocity for the site.
d. Characteristics of the uppermost aquifer.
e. Design basis flood events used for accident analysis.

5. Geology

a. Characteristics of soil types and bedrock.
b. Design basis earthquake magnitudes used for accident analysis.
c. Description of other geologic hazards, e.g. mass wasting.

The above information complements and is consistent with the information presented in the Environmental Report, Emergency Plan, and ISA summary prepared by the applicant. In contrast to these more detailed descriptions, the summary site description reviewed under this section is less detailed and more brief.

1.3.4 ACCEPTANCE CRITERIA

The site description summary will be considered acceptable if the following is included:

1. A brief description of the site geography, including its location relative to prominent natural and man-made features such as mountains, rivers, airports, population centers, schools, commercial and manufacturing facilities, etc.

2. Population information based on the most current available census data to show population distribution as a function of distance from the facility.

3. Appropriate meteorologic data. Applicant's presentation or discussion includes design basis values for accident analysis of maximum snow or ice load, and probable maximum precipitation. The applicant presents appropriate design basis values for

lightning, high winds, tornado, hurricane, and other severe weather conditions that are applicable to the site.

4. A description of the hydrology, and geology, including seismicity, for the area. Applicant describes the design basis flood event for which the plant may be safely shut down. This event is at least the 100 year flood for the site, and is consistent with U.S. Army Corps of Engineers flood plain maps. The applicant describes the maximum earthquake magnitude and peak ground acceleration at the site and its expected likelihood, in terms of return period at which the plant processes can be shut down safely with acceptable risk of radiological exposure to workers, public, and the environment. Applicant compares the design basis earthquake with the maximum earthquake accelerations expected on the site with a return period of 10,000 years. The purpose of the comparison is to evaluate the likelihood of the design basis earthquake to ensure that such an event is properly considered in the applicant's ISA.

Applicant's descriptions are consistent with the more detailed information presented within the ISA information in Chapter 3 of the application, the Environmental Report, and the Emergency Plan, if applicable. The information in the description is based on official assessments prepared by Federal, State, or local authorities.

1.3.5 REVIEW PROCEDURES

1.3.4.1 Acceptance Review

The staff review starts with a determination by the primary reviewer that the application provides the content as required by 10 CFR Part 70 regarding the site description for fuel cycle facilities, and that topics discussed in Section 1.3.3, "Areas of Review," have been addressed. The information in this section provides a general summary of the bases for evaluations completed in the ISA section of the application and is consistent with the applicant's environmental report and emergency plan. The applicant may include references to the more detailed data used to complete evaluations in the ISA. The primary reviewer reviews the information in the application for completeness.

If significant deficiencies are identified in the application, the applicant will be requested to submit additional material before the start of the safety evaluation. The detailed information necessary to support the site description summary will be included in the ISA section of the application.

For license renewals, the details necessary to support the information in the site description summary may be referenced to prior submittals or material included else where in the renewal application.

1.3.4.2 Safety Evaluation

The material to be reviewed in this section is informational, summarizing the reports and information which provide the bases for the ISA evaluations. The primary reviewer verifies that the information is acceptable using the acceptance criteria of this SRP, and accurately portrays

and is consistent with the information in the ISA summary, Environmental Report, Emergency Plan and other documents referenced by the applicant. No technical analysis is required, as the primary reference for the information is the ISA. If information being verified is found to be inconsistent from the primary source, the applicant is requested to submit clarifying information or corrections. This section may also need to be updated by the applicant based upon any information changes made in response to the staff's environmental, emergency management, and ISA reviews.

1.3.6 EVALUATION FINDINGS

The staff's review verifies that sufficient information has been provided in the license application to satisfy 10 CFR Part 70.22, "Contents of Applications," requirements with respect to the site description and that the information provided is consistent with the guidance in this SRP and information contained in other sections of the application. On the basis of this information, the staff concludes that this evaluation is complete and the applicant's site description is acceptable. The staff can document its review as follows:

The staff has reviewed the site description for [name of facility] according to the Standard Review Plan Section 1.3. The applicant has adequately described and summarized general information pertaining to (1) the site geography, including its location relative to prominent natural and man-made features such as mountains, rivers, airports, population centers, schools, and commercial and manufacturing facilities; (2) population information based on the most current available census data to show population distribution as a function of distance from the facility; (3) meteorology, hydrology, and geology for the site; and (4) applicable design basis events. The reviewer verified the site description to be consistent with the information used as a basis for environmental, emergency management, and ISA analyses.

1.3.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

2.0 ORGANIZATION AND ADMINISTRATION

2.1 PURPOSE OF REVIEW

The purpose of the review of the applicant's organization and administration is to ensure that management systems and structures are in place that provide reasonable assurance that the licensee plans, implements, and controls site activities in a manner that ensures the safety of workers, the public, and the environment. The review also ensures that the qualifications for key management positions are adequate.

2.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: None

Supporting: Primary reviewers for other SRP Chapters, e.g., technical area chapters and management measures chapters; Fuel Facility Inspection staff

2.3 AREAS OF REVIEW

The organizational structure and associated administrative program proposed by the applicant should include administrative policies, procedures, and management measures, qualifications of key management positions, along with a description of how these are deemed adequate to provide reasonable assurance that the health, safety, and environmental protection (HS&E) functions will be effective.

For new applicants, or already licensed plants undergoing major modifications, the applicant should address the integration of authorities and responsibilities among the process designers, the architect-engineering firm, the construction contractor, and the plant operator, as applicable, to provide assurance that they will function as needed on the HS&E-related tasks.

The application should address how the management measures ensure the establishment and maintenance of design and operations. The administrative policies and management measures should describe the relationships among major plant safety functions such as the ISA, configuration management, maintenance, quality assurance (QA), training, radiation safety, nuclear criticality safety, fire safety, chemical safety, environmental monitoring, emergency planning, audits and assessments, and incident investigations. The applicant should also describe its qualification criteria for education, training, and experience for key management positions. Management positions for which such criteria should be described include the plant manager, operations manager, shift supervisor, and managers for various safety and environmental disciplines. Qualification criteria should be described generally, in terms of academic credentials, formal continuing education, and work experience. For

example, "...bachelor's degree in nuclear engineering or related scientific or engineering field, with 5 years experience managing the operations of a nuclear fuel manufacturing facility."

2.4 ACCEPTANCE CRITERIA

2.4.1 Regulatory Requirements

A management system and administrative procedures for the effective implementation of HS&E functions is required by 10 CFR Part 70.22, 70.23, and other sections of Part 70, as revised,[1] concerning the applicant's corporate organization, qualifications of the staff, and the adequacy of the proposed equipment, facilities, and procedures to provide adequate safety for workers, the public, and the environment.

2.4.2 Regulatory Guidance

There are no regulatory guides specific to the organization and administration description of fuel cycle facilities.

2.4.3 Regulatory Acceptance Criteria

The application is acceptable if the following criteria are met. Appropriate commitments relevant to these criteria should be included in the applicant's safety program description.

New Facilities or Facilities Undergoing Major Modifications (In addition to the criteria listed below for existing facilities):

1. The applicant has identified and functionally described the specific organizational groups responsible for designing, constructing and operating the facility. Organizational charts are included in the application.

2. Clear, unambiguous management control and communications exist among the organizational units responsible for the design and construction of the facility. A corporate officer is responsible for HS&E activities.

3. The personnel to design, construct, and operate the facility have substantive breadth and level of experience and are appropriately available. The qualifications, responsibilities, and authorities for key supervisory and management positions with HS&E responsibilities, including the plant manager, operations manager, shift supervisor, and HS&E managers (or similar positions), are clearly defined in position descriptions that are accessible to all affected personnel and to the NRC, upon request.

[1] This reference is to the draft revision to 10 CFR Part 70, subject to on-going dialogue.

4. The applicant has described specific plans to transition from the design and construction phase to operations.

Existing Facilities:

1. Applicant has identified and functionally described the specific organizational groups responsible for designing and operating the facility. Organizational charts should be included.

2. The qualifications, responsibilities, and authorities of key supervisory and management positions with HS&E responsibilities including the plant manager, operations manager, shift supervisor, and HS&E managers (or similar positions), are clearly defined in position descriptions that are accessible to affected persons and to the NRC, upon request. A corporate officer is responsible for HS&E activities.

3. In the organizational hierarchy, the HS&E organization(s) is independent of the operations organization(s), allowing it to provide objective HS&E audit, review, or control activities. "Independent" means that neither organization reports to the other in an administrative sense. Both may report to a common manager. Lines of responsibility and authority are clearly drawn.

4. The individual delegated overall responsibility for the HS&E functions has the authority to shut down operations if they appear to be unsafe, and must in that case approve restart of shutdown operations. Typically, this individual should be at as high a management level as the production or operations manager and have direct line responsibility to the plant manager.

5. The activities essential for effective implementation of the HS&E functions are documented in formally approved, written procedures, prepared in compliance with a formal document control program.

6. The applicant should commit to a simple mechanism for reporting potentially unsafe conditions or activities to the HS&E organization and/or to upper management that is available for use by any person in the plant. Reported concerns are investigated, assessed, and resolved promptly.

7. Effective lines of communication and authority among the organization units involved in the engineering, HS&E, and operations functions of the facility are clearly defined.

8. The applicant has committed to establish formal management measures including configuration management, maintenance, quality assurance (QA), training and qualification, procedures, human factors, audits and assessments, incident investigations, and records management, as necessary and appropriate to ensure the availability and reliability of controls relied on for safety. The detailed guidance for these functions is addressed in separate SRP sections on the specific topic. The

applicant also describes how management assures, by formal procedures, that all applicable management measures are appropriately implemented for all structures, systems, and components that are considered items relied on for safety as defined by the safety program and its ISA.

9. Written agreements exist with off-site emergency resources such as fire, police, ambulance/rescue units, and medical services. This is addressed in more detail in Section 7.0, "Fire Safety," and Section 8.0, "Emergency Planning," of this SRP.

Commitments relevant to meeting the acceptance criteria described above are included in the applicant's safety program description.

2.5 REVIEW PROCEDURES

2.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the “Areas of Review” discussed in Section 2.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

2.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 2.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 2.4. The objective of the review is to ensure that the corporate-level management and technical support structure, as demonstrated by organizational charts and descriptions of functions and responsibilities, are clear with respect to assignments of primary responsibility. The primary reviewer consults with the NRC inspection staff to verify that the applicant’s management positions are adequately defined in terms of both numbers of persons and their responsibilities, authorities, and required qualifications.

The review process should consist of:

1. An examination of the applicant's organizational structure and administration as described in the application.

2. Site visits by one or more reviewers (with support from the NRC inspection staff, as appropriate) to review, discuss, and verify implementation of the management structure, systems, and administrative procedures.

The supporting staff reviewers determine, on the basis of the foregoing, the overall acceptability of the applicant's management system, management qualifications, organizational structure, and administrative procedures. To facilitate the review of the applicant's proposed organization and administration program, the reviewers should examine organization charts, position descriptions, corporate and plant policies, and the descriptions of administrative procedures and guidance documents concerning HS&E. The reviewers should make a determination whether the acceptance criteria of Section 2.4 are satisfied and then prepare an SER in accordance with Section 2.6.

2.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 2.4.1 and that the regulatory acceptance criteria in Section 2.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewer should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

The staff has reviewed the organization and administration for [name of facility] according to the Standard Review Plan Chapter 2.0.

[For new facilities] The applicant has described (1) clear responsibilities and associated resources for the design and construction of the facility and (2) its plans for management of the project. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] The staff has reviewed these plans and commitments and concludes that they provide reasonable assurance that an acceptable organization, administrative policies, and sufficient competent resources have been established or are committed, to satisfy the applicant's commitments for the design and construction of the facility.

[For operating and new facilities] The applicant has described its organization and management policies for providing adequate safety management and management measures

for the safe operation of the facility. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] The staff has reviewed these measures and concludes that the applicant has an acceptable organization, administrative policies, and sufficient competent resources are established to provide for the safe operation of the facility under both normal and abnormal conditions.

2.7 REFERENCES

1) Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* U.S. Government Printing Office, Washington, DC.

2) Proposed Revision to Code of Federal Regulations, Title 10, Part 70, *Domestic Licensing of Special Nuclear Material,* as revised.

3) NUREG-1324, *Proposed Method for Regulating Major Materials Licensees*, Sections 3.1, Organization Plan, and 3.2, Managerial Controls and Oversight, U.S. Nuclear Regulatory Commission, 1992.

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

NOTE

SRP CHAPTER 3 HAS BEEN REVISED TO ADDRESS SOME OF THE COMMENTS RECEIVED THROUGH MAY 1999. IT WAS NOT POSSIBLE TO COMPLETELY ADDRESS ALL OF THE COMMENTS RECEIVED DUE TO TIME CONSTRAINTS IMPOSED BY PUBLICATION DATES. ADDITIONAL COMMENTS ARE EXPECTED ON THIS CHAPTER. A SUBSEQUENT REVISION WILL ADDRESS ALL COMMENTS RECEIVED ON THIS CHAPTER.

3.0 INTEGRATED SAFETY ANALYSIS (ISA)

3.1 PURPOSE OF REVIEW

The purpose of the ISA review is to establish reasonable assurance that the applicant or licensee has:

1. Performed a comprehensive ISA of the fuel cycle facility and its processes using effective systematic methods.

2. Identified and evaluated all hazards and credible accident sequences in the ISA involving process deviations or other events internal to the plant (e.g., explosions and fires), and credible external events (e.g., floods, high winds, and earthquakes) that could result in consequences to the public, worker, or the environment of the types specified in 10 CFR 70.61.

3. Designated engineered and administrative items relied on for safety, and evaluated the set of items for each accident sequence to provide reasonable assurance, through preventive or mitigative measures, that the safety performance requirements of 10 CFR 70.61 are met.

4. Used competent staff in the ISA process.

5. Provided a formal system to manage changes to the ISA.

3.2 RESPONSIBILITY FOR REVIEW

Primary: LIB assigned reviewer

Secondary: Technical specialists in specific areas

Supporting: Fuel Facility Inspection Staff

3.3 AREAS OF REVIEW

Information about the licensee's ISA is contained in the license application, the ISA summary, and other ISA documentation. The application and the ISA summary are submitted to NRC whereas additional documentation of the ISA is available for NRC review at the facility site. The term "results of the ISA" includes all the ISA information that is submitted to NRC plus the additional supporting information that is found on-site. In general, the application contains information needed by the reviewer to understand the nature of the ISA process performed at the site, the qualifications of the team performing the ISA, the major results of the ISA, and the procedures for conducting and maintaining the ISA. The application provides licensee commitments that demonstrate the adequacy of the ISA program. The summary of the ISA provides a synopsis of the results of the ISA as specified in 70.65(b). Information contained in the ISA summary that also satisfies the information requirements in the application may be referenced in the application.

The staff reviews the application and the ISA results (ISA summary and other ISA documentation) to find reasonable assurance that the applicant has performed a systematic evaluation of the hazards and credible accident sequences. The review includes the makeup of the ISA team and the administrative and physical safety controls required to prevent or mitigate the consequences of accidents. The review boundary includes those accidents that result in a release of licensed radioactive material or an inadvertent nuclear criticality event. In addition, the staff reviews accidents involving hazardous chemicals when the chemicals are composed of, or produced from the processing of, licensed radioactive material; or if the accident has the potential to jeopardize the safety of regulated activities. An event sequence having consequences less than those identified in 10 CFR 70.61(c) would not require further consideration within the ISA. The areas of review are as follows:

1. The site description (see Section 1.3, "Site Description") concerning those factors that could affect safety, such as geography, meteorology (e.g., high winds and flood potential), seismology, and demography.

2. The facility description concerning features that could affect potential accidents and their consequences. Examples of these features are facility location, facility design information, and the location and arrangement of buildings on the facility site.

3. The description of each process analyzed as part of the ISA. Specific areas reviewed include basic process function and theory, major components ! their function and operation, process design and equipment, and process operating ranges and limits.

4. The applicant's commitment to compile and maintain a current and accurate set of process safety information (PSI) including information on the hazardous materials, technology, and equipment used in each process. The applicant should explain this activity in detail in the description of its configuration management program (Section 11.1, "Configuration Management").

5. The description of the applicant's requirements for ISA team training and qualifications (Section 11.3, "Training and Qualification").

6. The ISA method used for each individual process node and the justification for its selection. For purposes of this review, the ISA begins with an identification of hazards (chemicals,

radiological materials, fissile materials, etc.) that may present a potential threat to the public, facility workers, or the environment. Based on a systematic analysis of each plant process, the ISA Process Hazard Analysis (PHA) identifies a set of individual accident sequences or process upsets that could result from the hazards. The review of the ISA methodology includes evaluating the applicant's methods in the following specific areas:

a. Hazard identification.

b. Process hazard analysis (accident identification).

c. Accident sequence construction and evaluation.

d. Consequence determination and comparability to 10 CFR 70.61.

e. Likelihood categorization for determination of compliance with 10 CFR 70.61.

7. The narrative description, process hazard analysis documentation, and the tabular summary of the ISA results in the following specific areas:

   a. The list of hazardous materials and conditions resulting from the Hazard Identification task.

   b. The Hazard Interaction Matrix table [see reference AIChE 1992, section 3.3].

   c. Accident sequences identified by the ISA systematic Process Hazard Analysis.

   d. Unmitigated and mitigated consequences of each postulated accident to facility workers or the public.

   e. Comparisons of the consequences of each postulated accident to the consequences of concern identified in 10 CFR Part 70.61.

   f. Identification of engineered and administrative controls involved in each accident sequence.

   g. Assignment of accident sequences to likelihood categories and comparison to 10 CFR 70.61 requirements.

8. The description of the engineered and administrative safety controls, and mitigative barriers used to maintain safe operation of the facility to ensure that, for each accident sequence, the controls are commensurate with 10 CFR 70 requirements as interpreted in the acceptance criteria of section 3.4 below. These criteria are risk informed in that systems of controls applied to accident sequences having more severe consequences are to be correspondingly more reliable. The applicant should also commit to maintain safety controls and mitigative barriers available and reliable for high and intermediate risk accident sequences.

9. The management measures (see definition in Glossary) applied to each safety control needed to conform to the requirements of 10 CFR 70.62(d). Those management

measures that are generically applied to all safety controls or to specified classes of controls may be described in Section 11, “Management Controls Systems,” or in Sections 4 through 7 and 9, which cover specific safety disciplines. However, since the ISA identifies the safety controls as such, and provides other information needed to apply management measures in a graded manner, the information from the ISA summary and other ISA documentation needed to implement these systems should be reviewed.

For accident sequences evaluated as potentially having the consequences specified in 70.61, but meeting the likelihood requirements of 10 CFR 70.61 without controls, staff reviews the basis for the applicant evaluation of the sequence as being of acceptably low likelihood. Typically such accident sequences involve very low likelihood natural phenomena or other initiating events.

10. The facility procedures for conducting and maintaining the ISA. The object of this review is to ensure the overall integrity of the ISA as a current and accurate safety basis for the facility. Specific review areas include the applicant's procedures for: (1) performing and updating the ISA, (2) review responsibility, (3) documentation (including provisions for updating NRC on changes to controls or seeking NRC approval of changes per 70.72, and (4) maintenance of ISA records per 70.62(a)(2). The integrity of the ISA procedures should be controlled by the applicant's configuration management program.

3.4 ACCEPTANCE CRITERIA

3.4.1 Regulatory Requirements

The requirement to perform an Integrated Safety Analysis (ISA) is specified in 10 CFR 70.62. 10 CFR 70.62(c) specifies requirements for the tasks comprising the ISA and the demonstration that items relied on for safety meet the safety performance requirements of 70.61. 10 CFR 70.72 states requirements for keeping the ISA and its documentation current when changes are made to systems, structures, and components.

3.4.2 Regulatory Guidance

Guidance applicable to performing an ISA and documenting the results is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document." A sample ISA Summary for one process is also available to illustrate an acceptable form and content.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA are based on meeting the relevant requirements in 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material." The ISA will form the basis for the safety program by identifying accidents of concern, designating controls and management measures, and evaluating the likelihood of each accident sequence for compliance with 70.61. The staff will accept the ISA, the designation of controls, and the management of the ISA process if the reviewer finds the following criteria are met:

1. The description of the site for processing nuclear material is considered acceptable if the applicant includes or references the following safety-related information in the application:

   a. A description of the site geography, including its location from prominent natural and man-made features such as mountains, rivers, airports, population centers, possibly hazardous commercial and manufacturing facilities, etc. adequate to permit evaluation of the likelihood and magnitude of consequences of concern.

   b. Population information, based on recent census data, that shows population distribution as a function of distance from the facility adequate to permit evaluation of regulatory requirements, including exposure of the public to consequences listed in 10 CFR 70.61.

   c. Characterization of natural phenomena (e.g., tornadoes, hurricanes, and earthquakes) and other external events sufficient to assess their impact on plant safety and to assess their likelihood of occurrence. The discussion identifies the design basis events for the facility and indicates which events are considered incredible and the basis for that determination. The assessment also indicates which events could occur without adversely impacting safety.

The level of detail for this material is greater than that which would be acceptable in the general information in Chapter 1.

2. The description of the facility is considered acceptable if the applicant identifies and describes the general features that are relied on or required for safety. If such information is available elsewhere in the application, reference to the appropriate sections is considered acceptable. The information provided should adequately support an overall understanding of the facility structure and its general arrangement as it pertains to the ISA. As a minimum, the applicant adequately identifies and describes:

   a. The facility location and the distance from the site boundary in all directions, including the distance to the nearest resident and distance to boundaries in the prevailing wind directions.

   b. Design information regarding the resistance of the facility to failures caused by credible external events, when those failures may produce consequences of concern.

   c. The location and arrangement of buildings on the facility site.

3. The description of the processes analyzed as part of the ISA is considered acceptable if it describes the following features sufficiently to permit: 1) an evaluation of the completeness of the hazard (accident) identification task, and 2) an evaluation of the likelihood and consequences of the accidents identified. If the information is available elsewhere in the application and is adequate to support the ISA, reference to the appropriate sections is considered acceptable. The information provides an adequate explanation of how the safety controls reliably prevent the process from exceeding safety limits for each case identified in the ISA results where they are needed.

   a. Basic process function and theory. This information includes a general discussion of the basic theory of the process.

b. Major components ! their function and operation. This information includes the general arrangement, function, and operation of major components in the process. It includes process schematics showing the major components and instrumentation and, if appropriate, chemical flow sheets showing compositions of the various process streams.

c. Process design and equipment. This information includes a discussion of process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate understanding of the results of the ISA. It includes schematics indicating safety interrelationships of parts of the process. In particular, either schematics or descriptions indicating the location and geometry of Special Nuclear Materials, moderators, and other materials in the process are sufficient to permit an understanding of the adequacy of controls on mass, geometry, moderation, reflection, and other criticality parameters affected by geometry.

d. Process operating ranges and limits. This information includes the operating ranges and limits for measured process variables (e.g., temperatures, pressures, flows, and compositions) used in engineered or administrative controls to ensure safe operation of the process. The process operating limits and ranges are considered acceptable if they are consistent with those evaluated as adequate for safety in the ISA. One acceptable way of presenting this information is as a tabular summary of all safety controls grouped according to hazard type, i.e. nuclear criticality, radiological hazards, chemical hazards, etc., as shown in Appendix A, Table A.3-7.

4. For purposes of conducting an ISA, the applicant's Process Safety Information is considered acceptable if the applicant commits to maintain, at a minimum, the following information current and accurate:

   a. Hazardous material information including toxicity information, permissible exposure limits, physical data, reactivity data, corrosivity data, and stability data (thermal and chemical).

   b. Process technology information including block flow diagrams or simplified process flow diagrams, process chemistry, maximum intended inventory, and safe upper and lower limits for parameters controlled for safety reasons, such as temperatures, pressures, flows, and compositions.

   c. Process equipment information including materials of construction, piping and instrumentation diagrams (P&IDs), electrical classification, relief system design and design basis, ventilation system design, design codes and standards used, material and energy balances, and safety systems (e.g., interlocks, detection systems, and suppression systems).

5. The ISA team for each process analyzed is considered acceptable if the following criteria are met:

   a. The ISA team has a team leader who is formally trained and knowledgeable in the ISA methodology chosen for the hazard and accident evaluations. In addition, the team

leader can demonstrate an adequate understanding of all process operations and hazards under evaluation, but is not the cognizant engineer or expert for that process.

b. At least one member of the ISA team has thorough, specific, and detailed experience in the process under evaluation.

c. The team represents a variety of process operating and engineering design experience, in particular, radiation safety, nuclear safety, fire protection, and chemical safety disciplines.

d. A manager provides overall administrative and technical direction for the ISA.

6. The descriptive summary of the ISA methodology is considered acceptable if it describes the methods used for each ISA task, and the basis for selection of each method, so that the adequacy of the method is clear and appropriate according to the criteria described in NUREG-1513 for selection of ISA methods. Specific acceptance criteria for the ISA methodology are as follows:

   a. The hazard identification method selected is considered acceptable if it:

      i. Provides a list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations (e.g., loss of containment of licensed nuclear material). The list includes maximum intended inventory amounts and the location of the hazardous materials at the facility.[2]

      ii. Determines potential interactions between materials or between materials and conditions that could result in hazardous situations.

   b. The process hazard analysis (accident sequence identification) method selected is considered acceptable if:

      i. Its selection is consistent with the guidance provided in NUREG-1513. For methods used by the applicant but not addressed in NUREG-1513, the applicant provides justification and references for their use.

      ii. It adequately address all the hazards identified in the hazard identification task of section 6.a above. The applicant identifies and justifies any hazards eliminated from further consideration.

      iii. It provides reasonable assurance that the applicant identifies all significant accident sequences (including the controls used to prevent or mitigate the accidents) that could result in consequences of concern identified in §70.61[3].

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[2]At least the following hazardous materials should be included in the inventory list if present on-site: ammonia, fines (UO_2 dust), flammable liquids and gases, fluorine, hydrofluoric acid, hydrogen, nitric acid, organic solvents, propane, uranium hexafluoride, and Zircalloy.

[3]The release of hazardous chemicals is of regulatory concern to NRC only to the extent that such hazardous releases result from the processing of licensed nuclear material or have the potential for adversely affecting radiological safety.

iv. It takes into account the interactions of identified hazards and proposed controls, including system interactions, to ensure that the overall level of risk at the facility is consistent with the requirements of §70.61 and appropriately limited.

v. It addresses all modes of operation including startup, normal operation, shutdown, and maintenance.

vi. It addresses hazards resulting from process deviations (e.g., high temperature, high pressure), initiating events internal to the facility (e.g., fires or explosions), and hazardous credible external events (e.g., floods, high winds, and earthquakes, airplane crashes). The applicant provides justification for its determination that certain events are incredible and, therefore, not subject to analysis in the ISA.

vii. It adequately considers initiation of, or contribution, to accident sequences by human error by appropriate use of human-systems interface analysis.

viii. It adequately considers common mode failures and system interactions in evaluating systems that are to be protected by double contingency.

c. The application demonstrates that valid consequence evaluation methods have been used, as described in the appropriate safety chapters of the license application (e.g., Section 5.0, "Nuclear Criticality Safety," Section 6.0, "Chemical Safety"). Acceptable methods of consequence evaluation are described in Nuclear Fuel Cycle Facility Accident Analysis Handbook, NUREG/CR-6410, March 1998.

d. The applicant uses, and submits adequate documentation of, an effective method for evaluating the adequacy of items relied on for safety in all identified accident sequences. This evaluation method is considered acceptable if:

i. For nuclear criticality accident sequences, it can demonstrate adherence to the double contingency principle, including reasonable assurance that common failure modes are accounted for (see Section 3.4.3.8), or

ii. It can demonstrate compliance with the graded protection criteria of 10 CFR 70.62(a) consistent with the guidance in the Appendix A. Or, for individual accident sequences not conforming to the guidance in Appendix A, specific and adequate justification showing conformance to 10 CFR 70.61 is provided.

7. ISA RESULTS: The documentation of the ISA results, consisting of both the ISA Summary and the in-plant documentation of results, is acceptable if it is sufficient to demonstrate that the following three top level criteria have been met:

a) completeness in identifying all accident sequences,
b) acceptable evaluation of consequences, and
c) acceptable evaluation of likelihood.

That is, the documentation of results is acceptable if it demonstrates:

(a) completeness of the ISA in identifying all hazards and accident sequences that might be capable of producing consequences of concern. This means that all accidents exceeding the minimum consequence levels of 10 CFR 70.61 including: those that involve releases of licensed material or hazardous chemicals produced from licensed material, all unplanned radiation exposures, and all nuclear criticality accidents have been identified. The primary criterion for completeness is that the systematic method chosen was correctly applied. During the PHA phase accidents will be identified whose consequences may initially be unknown, then later are analyzed and shown to be beneath the minima of concern. The ISA documentation must show which such accidents have been eliminated due to insufficient consequences, otherwise the completeness of those identified cannot be evaluated. Large groups of events of a similar nature and clearly having consequences below the level of concern may be described as a single item, provided the definition of the group is sufficiently clear as to which accidents are included, so that completeness is evident;

(b) correct evaluation of the consequences of each accident sequence and comparison to the consequence levels of concern in 10 CFR 70.61, and

(c) evaluation showing, with adequate basis, compliance with the likelihood requirements of 10 CFR 70.61.

Supporting criteria for acceptable ways of complying with each of these three top level criteria follow.

a. COMPLETENESS.

The information submitted is acceptable for showing completeness in identifying accident sequences and evaluation of consequences if:

i. The summary of the hazard identification results provides:

1) A list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations. The list includes maximum intended inventory amounts and the location of the hazardous materials at the site.

2) A hazards interaction table showing potential interactions either between materials or between materials and conditions that could possibly result in hazardous situations.

ii. The ISA results documentation provides either:

1) A tabular summary description of the accident sequences identified in the process hazard analysis. The tabular description consists of one row for each accident sequence. Accident sequences initiated by the same type of event, and consisting of the same sequence of control failures, and resulting in the same consequence category are summarized as a single row. This row lists the initiating event, the controls or barriers that must fail in order for the accident to occur, and the level of unmitigated consequences, if all controls fail. The listing clearly indicates the sequence and linkage between each initiating event, the controls designed to

prevent or mitigate consequences of concern, and the resulting consequences when these controls fail. The tabular summary identifies the severity level of each type of consequence (radiological, criticality, chemical, environmental) according to the values defined in 10 CFR 70.61. Information sufficient for evaluation of compliance with the likelihood requirements of 10 CFR 70.61, such as likelihood indices are tabulated. Appendix A, Table A-1, provides an acceptable way of presenting this information.

OR

2) A set of logic diagrams, such as fault trees or event trees for each process, presenting the same information as in 1) above.

In the tabular summary or diagrams showing accident sequences, it is not necessary to list as a separate sequence every conceivable permutation of the accidents. The listing has three purposes: 1) to show completeness, 2) to permit evaluation of likelihood (adequacy of controls), and 3) to identify controls relied on to prevent and mitigate accidents. Accidents having characteristics that all fall in the same categories can be grouped as a single line item in the table, if: a) the initiating events have the same type of effect on the system, b) they all consist of failure of the same controls, c) they all result in violation of the safety limit on the same parameter, and d) they all result in the same type and severity category of consequences. A primary purpose of showing completeness is to assure that existing safety controls are adequate. Once this has been shown for a class of accidents having the same characteristics, it is not necessary to distinguish among the different types. On the other hand, if a different initiating event poses a different type of challenge to a safety control, then it should be listed separately, because it may reveal a weakness of the control.

To demonstrate completeness, it may be necessary to describe certain accidents evaluated as incredible events, when this is not obvious. Justification for their evaluation as incredible should be provided.

b. CONSEQUENCES.

The information submitted is acceptable for showing adequate evaluation of consequences of accidents if:

i. The ISA results documentation at the plant includes a description of each accident that includes an estimate of its quantitative consequences (doses, chemical exposures, criticality) in a form that can be directly compared to the consequence levels in 10 CFR 70.61 or includes a reference to a calculated value that applies to that accident; and

ii. The ISA Summary includes a brief description of each process that also summarizes the accident consequences in that process by giving the maximum calculated exposure values for each type of chemical and the maximum radiological dose, other than from criticalities, to both workers and the offsite public, and whether a criticality accident was identified in that process.

The ISA results documentation must show that all accident sequences have a likelihood and consequences, such that the safety performance requirements of 10 CFR 70.61 are met. Showing the consequences for each accident can be done using a tabular summary as shown in Appendix A, Table A-1, by a narrative list of all accident sequences, or by annotated logic diagrams.

Consistent with the guidance in the following paragraph, criticality accidents will normally be high consequence events because the dose will exceed 100 rem to nearby workers (see Section 5.0, "Criticality Safety"). For processes with effective engineered shielding, criticalities may produce very low doses to workers. However, as stated in the regulation, notwithstanding the effectiveness of shielding or other mitigative features, primary reliance must be on prevention of criticalities. However, when shielding is used, it is acceptable that preventive measures of lower reliability be used. That is, shielded criticality events need not be highly unlikely.

In assessing the consequences of nuclear criticality accidents to workers, since a typical criticality of 10^{17} fissions produces a dose of about 450 to 1000 rem at 2 meters, it is acceptable to assume that, absent shielding, criticalities will exceed the 100 rem threshold. Hence, all such criticalities would be categorized as "high consequence" accidents in the terminology of 10 CFR 70.61. Any reduction of the dose from a criticality accident to a value below 100 rem is acceptable if due to reliable engineered features, such as shielding. Administrative controls alone would not normally be considered of adequate reliability. In evaluating shielding, a criticality of a conservative credible magnitude must be assumed. The Nuclear Fuel Cycle Facility Accident Analysis Handbook, NUREG/CR-6410, March 1998, provides methods for estimating magnitudes of criticality events.

c. LIKELIHOOD

The ISA documentation is acceptable for showing compliance with 10 CFR 70.61 and 70.62(a) if:

1) It contains an evaluation of the likelihood of each accident that is adequately supported, and
2) these evaluated likelihoods comply with 70.61.

The likelihood requirements stated in 10 CFR 70.61 are that accidents resulting in consequences of concern in 70.61(b), "high consequences", be "highly unlikely"; and those resulting in consequences in 70.61(c), "intermediate consequences", be "unlikely".

Acceptance criterion 1 above means that, to be acceptable, the evaluation of the accidents must be supported by use of a methodology that provides reasonable assurance that the items relied on to prevent or mitigate the accident are sufficient to achieve the regulatory requirement of unlikeliness. Such methods must be systematic, consistent among different practitioners, consistent with the actual history of failure events at the plant, and consider all the factors that affect the reliability of items. As a minimum, the method should consider the factors of redundancy, independence, concurrency, and human error. To achieve consistency, objective written methods, data, and criteria should be established to be followed by ISA Team members evaluating likelihood compliance.

Acceptance criteria 2 above means that, ultimately, the conclusion of an evaluation must clearly assign the accident as “highly unlikely” or “unlikely” as required. This means that the terms, “unlikely” and “highly unlikely”, require interpretation. The applicant may provide in the ISA submittal, a definition and basis for these terms. One basis acceptable to the staff is provided in the following.

The text and tables in Appendix A describe an acceptable method for establishing likelihoods based on estimated frequencies of failure.

LIKELIHOOD CRITERIA

The terms, “highly unlikely” and “unlikely”, are inherently quantitative in nature. That is, the underlying concept is that events have a certain likelihood of occurrence in any one year; and adequate safety performance means this likelihood be sufficiently low. The obvious questions are:

1) What annual frequency would qualify as “unlikely” or “highly unlikely” respectively?
2) How can compliance with the requirements be demonstrated?

10 CFR 70.61 safety performance likelihood requirements are stated in qualitative rather than quantitative form. Thus staff should not interpret these requirements as mandating that quantitative analysis be done to show compliance. However, quantitative analysis of likelihoods is one acceptable method of showing compliance. If quantitative analysis is performed, accident sequence frequencies should be determined using established methods and input values consistent with industry performance. Because quantitative methods would be acceptable, there follows a discussion of acceptable accident frequency values based on Commission guidance. Following this discussion of frequencies, criteria for acceptable non-quantitative methods will be given.

QUANTITATIVE LIKELIHOOD EVALUATION

Quantitative Evaluation Methods

Standard methods for quantitative evaluation of the frequency of accidents can be found in works on reliability engineering and probabilistic risk assessment. Such methods require input information concerning failure and repair rates for basic events. These basic events may be external or internal initiating events or failures of items relied on for safety. Quantitative credit should not be taken for the low likelihood of an event without justification. One justification is that the event is failure of an item relied on for safety that is subject to management measures (e.g. maintenance, training) to assure meeting its reliability goal. Another justification is that the event has inherently low likelihood that cannot reasonably be increased by human intervention.

Quantitative Acceptance Criteria

There are two safety performance measures established as part of the NRC Strategic Plan that bear on the question of how reliable safety controls must be. These goals thus bear directly on the question of acceptance criteria for safety controls identified in the ISA’s to be done at fuel cycle facilities. The two safety performance measures are: 1) No inadvertent

nuclear criticalities, and 2) no increase in reportable radiation releases. Unshielded criticality events can be expected to produce doses to workers exceeding the 100 rem value defining "high consequences". Hence, high consequence events are tied to this first safety performance measure. That is, an acceptable interpretation of the 70.61 requirement that high consequence events be "highly unlikely" should be consistent with the goal of "no inadvertent nuclear criticalities". This cannot mean zero likelihood, but neither can it mean that criticalities are expected frequently.

The second Commission safety performance measure refers to the requirements for Abnormal Occurrence reports by the NRC to Congress of radiation releases. One of these Abnormal Occurrence reporting criteria is 25 rem exposure to any adult. In terms of 70.61, 25 rem is an intermediate consequence event for a worker, and a high consequence event for the offsite public. Hence, the 70.61requirement that intermediate consequence accidents be "unlikely" is constrained by the Commission goal of "no increase" in the rate of 25 rem doses.

The current 1997 five year average of reportable radiation exposures (25 rem) is 0.4 per year. If no increase is to be permitted, then the contribution of fuel cycle facilities, which in the past has likely been zero, should be at most a small fraction of this 0.4 per year. For example, let the fuel cycle industry be allocated 10% of this value, hence 0.04 per year. If there are about 10 fuel cycle facilities, this is 0.004 per facility per year.

Similarly, to achieve no inadvertent criticalities, the expected frequency per accident per year must be sufficiently low. Let us say that, for the whole industry we wish to have a likelihood of criticality no more than once in 100 years. This would appear to be about as high a value as is tolerable for be consistent with the Commission goal. For an industry of 10 facilities, 0.01 per year is 0.001 per facility per year. Note that this is less than the 0.004 per facility per year goal for offsite doses exceeding 25 rem derived above.

Considering the above, a consistent set of quantitative goals would require that the sum of the frequencies of all accident sequences at a facility be less than:
1) 0.001 per facility per year for high consequence events, and
2) 0.004 per facility per year for intermediate consequence events.

It should be noted that the safety performance requirements of 70.61 are applied to each individual accident identified in the ISA. If an applicant chooses to use quantitative methods for evaluating compliance with 70.61, then summing the accident frequencies for the whole facility and showing compliance with the above numerical goals is one acceptable way of demonstrating compliance with the requirements.

NON-QUANTITATIVE LIKELIHOOD EVALUATION

In order that each accident sequence have sufficiently low likelihood to comply with 70.61 it is necessary that the system of safety controls (IROFS) designed to make the likelihood low have certain reliability characteristics. These characteristics include redundancy, independence, low failure rate, rapid detection of failures, and rapid restoration or repair. Qualitatively, the system of controls preventing an accident is sufficient to make it highly unlikely if it has double contingency protection as interpreted by the NRC staff. Double contingency protection can be achieved by having two independent highly reliable controls, or a larger number of redundant controls of equivalent system reliability. Qualitatively, the system of controls preventing an

accident is sufficient to make it unlikely if it has at least one highly reliable control, or multiple redundant controls of equivalent system reliability.

For an accident sequence with unmitigated consequences in the high consequence category of 70.61, adherence to double contingency is acceptable. Adherence to double contingency requires that at least two unlikely, independent, and concurrent changes in process conditions are necessary before a criticality accident can occur. If double contingency is not feasible, then the controls should exhibit sufficient redundancy and diversity to make criticality comparably unlikely.

For an accident sequence that results in the intermediate consequence category of 10 CFR 70.61, at least a single unlikely event must occur before the unmitigated consequences of the accident occur. The following is a logical deduction from the set of safety performance requirements; namely, that a mitigative control applied to a sequence must reduce the consequences below the limits defining the lower bound of the category in order to be credited in determining compliance with 70.61.

To show qualitative compliance with the likelihood requirements, the applicant must describe the qualitative likelihood evaluation method and criteria that have been used. The results of applying this method and criteria must then be documented for each accident sequence identified in the accident identification (PHA) phase of the ISA. The evaluation method must be systematic and sufficiently objective to allow different teams to produce consistent results. It is not adequate merely to have the ISA Team express a holistic judgement that the system of IROFS preventing a given accident makes it sufficiently unlikely. Such a method lacks consistency and objectivity and cannot be evaluated. The double contingency principle identifies the reliability characteristics required but does not provide criteria for when a process change is sufficiently “unlikely” to qualify.

The acceptance criterion for a non-quantitative likelihood evaluation method is that it include evaluation of each of the reliability characteristics of the system of controls. These characteristics to be evaluated are:

redundancy,
independence,
concurrency of the system,
likelihood of each of the individual “process changes”.

Detailed acceptance criteria for each characteristic are given below.

Redundancy

Redundancy refers to process designs where multiple items relied on for safety must fail before an accident can occur. An effective way to make accidents highly unlikely is to provide sufficient redundancy. Double contingency is a concept that includes redundancy as one element. It may appear that double contingency only requires a twofold degree of redundancy. This is not strictly true. Some controls used to prevent accidents are not sufficiently reliable on their own to make the undesired process change qualify as “unlikely”. This is particularly true when relying on administrative controls. By administrative is meant procedures requiring correct action by an operator. When using such low reliability controls, process parameters are

often controlled by multiple redundant items. Though no one of them would qualify alone as "unlikely" to fail, taken together they make the process change unlikely. Thus, to achieve double contingency may require a degree of redundancy greater than two. Two highly reliable engineered controls may be sufficient, but a greater number of controls is needed if each is of lower reliability.

Independence

Independence must be evaluated when redundancy is relied upon. Two events are independent if the likelihood of occurrence of each does not depend on the other. If independence is not achieved, then the likelihood of both failures may not be as low as one estimates. Independence means no common cause, no shared elements, and nothing else that could cause loss of both functions. There are checklists and other methodological tools for performing common cause evaluations of sets of controls. Ideally these methods should be used. In any case, independence should be evaluated. Controls that act upon the same process parameter may be subject to a single point failure that bypasses or overwhelms both. Processes which rely on correct action by an operator may be vulnerable to a single point failure that is an incorrect action by that operator. Protecting against this type of operator error may require physical locks or other means of preventing any single individual from taking an action that could be incorrect.

Concurrency

Any non-quantitative method for evaluating redundant systems of safety controls should take credit for lack of concurrency of control failures. Accidents often require that two process changes occur, each a change in the state of the system. The first change places the system in a certain state, for example, a critical mass accumulates. The second change, for example, addition of moderator, must occur while this first state still exists. If the first state is detected and corrected rapidly, it is much less likely that the second event will occur while the system is vulnerable. Thus for such active redundant systems, the evaluation methodology should include evaluation of the time to detect and correct failures. These time periods are referred to as "surveillance intervals" and "repair times". The total of these two for the first failure should be much shorter than the mean time between failures of the second control.

Another way of saying the same thing is that systems having items that may fail during the life of the plant require at least annual surveillance. Similarly, systems containing items known to fail frequently must have virtually continuous surveillance. This is not necessarily difficult because many processes are continuously manned during operation, failures are obvious, and restoration is quick. It can also be achieved by fail safe devices or by continuous automatic monitoring. The point is that the evaluation must explicitly consider surveillance and repair times. Without surveillance, failure of redundant systems containing items which can fail cannot be considered highly unlikely.

Likelihood

As stated earlier, the number of redundant items needed to make an accident highly unlikely depends on how unlikely failure of each redundant item is. All items are not created equal. In general, certain types of items are less likely to fail than others. A better way of saying this is that items with certain characteristics can more easily be made reliable. The usual hierarchy

is: passive engineered controls, active engineered controls, enhanced administrative controls, and simple administrative controls. Among administrative controls another such hierarchy is: enhanced prohibitions, simple prohibitions, enhanced positive actions, and simple positive actions required for safety. Although the reliability of safety items can be roughly categorized in this way, a better way is to define groups of items graded according to their safety significance. For instance the terms “safety equipment”, “safety related equipment”,”high reliability equipment”, “process features relied on for safety”, etc. may be used. Equipment or features in these groups then receive sufficient management measures (e.g., maintenance, surveillance, configuration management) to assure that they achieve a reliability appropriate to their group. The point is that, to be acceptable, a method for non-quantitative evaluation of accident sequences requires that the reliability of individual safety items be assured by characteristics or measures whose presence and relative effectiveness can be objectively determined.

Appendix A describes a method for demonstrating compliance with the likelihood requirements of 10 CFR 70.61. This method, though derived from and related to underlying frequencies of failure, can be applied as a purely qualitative method.

8. The “list describing items relied on for safety” required by 10 CFR 70.62(c)(vi) is acceptable if:

   1) it includes all items relied on for safety in the identified accident sequences; and

   2) the description of the items relied on for safety, their management measures, and the associated safety limits and margins is adequate to permit a determination of compliance with 10 CFR 70.62(c)(vi); and

   3) information concerning the assignment of management measures to safety controls is adequate to show compliance with 10 CFR 70.62(d).

Acceptance criteria 1) through 3) above are explained in greater detail below.

1) ALL ITEMS: The primary function of the “list describing all items relied on for safety” is to document the safety basis of all processes in the facility to assist in assuring that these items are not degraded or removed without a justifying safety review. Thus the key feature of this list is that every item relied on for safety be included. No item, aspect, feature, or property of the processes that is needed to show compliance with the safety performance requirements of the regulation may be left off this list.

For example, if a process upset is required before an accident may occur, and if, in showing compliance with 70.61 reliance is placed on the fact that this process upset is an unlikely event, then those features of the process that assure that the upset is of low frequency are an item relied on for safety. Similarly, if the dimension or the material composition of a piece of process equipment is essential to preventing an accident, then that dimension or material is an item relied on for safety. In such cases, only those dimensions, features, or properties of the process that are essential to the safety function are items relied on for safety. It is essential that such process features be clearly identified so that a description of their safety function is available to safety reviewers for change control.

Items relied on for safety include both hardware safety controls and administrative controls. All such items must be listed, no matter how low their safety significance, if they are relied on to demonstrate compliance with the safety performance requirements of 70.61. Such items may assure compliance by making the accident unlikely or by mitigating its consequences.

2) THE DESCRIPTIONS OF ITEMS: The essential features of each item relied on for safety (IROFS) that are required to achieve adequate reliability should be described. Sufficient information should be provided about hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability. If the IROFS is an administrative control, the nature of the action or prohibition involved must be described sufficiently to permit an understanding that, in principle, adherence to it should be reliable.

3) MANAGEMENT MEASURES: The description of each item must contain any information needed to identify how the management measures, such as maintenance, training, configuration management, etc. of 10 CFR 70.62(d) are applied to it. If a system of graded management measures is used, the grade applied to each control should be determinable from information provided. To show compliance with the performance requirements of 10 CFR 70.61, the description of the items relied on for safety and the management measures applied to them, must show how they meet all applicable provisions of the Baseline Design Criteria as described in Sections 4 through 7 and Section 11, or a lesser set of measures if justified. The primary justification for lesser management measures is lower risk significance.

One example of a tabular description of IROFS meeting these criteria is Table A-7 in Appendix A.

9. The description of the facility procedures for conducting and maintaining the ISA is acceptable if it includes: management policies, organizational responsibilities, administrative controls, and procedures governing the performance, review, and approval of the initial ISA and any revisions to the ISA. The applicant commits to evaluating the need for updating the ISA to reflect changes using a team with similar qualifications to the team that originally prepared the ISA for the system under review. In addition, the applicant commits to maintain the ISA under an adequate configuration management function. The applicant also identifies updates to the table on controls necessary to ensure safety, as well as seeks prior approval for any changes that raise unreviewed safety questions or increase the level of risk. Administrative controls ensure the independence of reviewing organizations and individual reviewers. The applicant establishes procedures to control records and supporting documentation concerning the ISA.

3.5 REVIEW PROCEDURES

3.5.1 Acceptance Review

The primary reviewer will review the application to determine if it contains the topics and information discussed in Section 3.3, “Areas of Review.” If significant deficiencies are identified in the application, the applicant will be requested to submit additional information before the start of the safety evaluation. The primary reviewer will then determine that the applicant has provided the information required. If necessary, a

request for additional information to the applicant will be prepared in conjunction with the licensing project manager.

3.5.2 Safety Evaluation

1. The staff reviews the applicant's description of the facility to determine if adequate information is presented to provide an understanding of those factors that could pose a hazard to the facility. The reviewer reviews the types, frequency, and severity of specific external hazards (such as locations of nearby airports, rail lines, port facilities, other nuclear or chemical facilities, dams, rivers, etc.) identified in the application. The reviewer similarly reviews natural external event hazards, such as severe weather conditions, hurricanes, earthquakes, floods, tornadoes, that are specific threats to the site.

2. The staff reviews the applicant's description of the facility to determine that the applicant has adequately discussed the features that could affect potential accidents and their consequences. The reviewer should verify that the applicant has provided information describing the location and arrangement of buildings at the site and their distance from the site boundary and nearby population. The reviewer should also determine that design criteria for the facility are justified on the basis that (1) they are sufficient to withstand the effects of credible external events that could occur at the site or (2) the consequences of such credible external events are acceptable, given their expected frequency of occurrence.

3. The staff reviews the applicant's description of each process analyzed in the ISA to determine that it provides an adequate understanding of process function and theory, as well as major component function and operation. The staff also reviews information provided on process design, equipment, and instrumentation to determine that it is sufficient to understand the results of the ISA.

4. The staff reviews the applicant's commitment to compile and maintain current and accurate process safety information on hazardous materials, process technology, and process equipment.

5. The staff reviews the applicant's description of the ISA team to determine the adequacy of the makeup of the team and qualifications of the team leader and team members. The reviewer should determine that the qualifications of the team meet the acceptance criteria in Section 3.4.3.5.

6. The staff reviews the applicant's description of the ISA methodology selected to verify that the applicant has cogently described the methodology (i.e., the methods used for hazard identification, hazard analysis and accident identification, accident consequence determination, and accident sequence evaluation) and the bases for its choice. The reviewer also verifies that the acceptance criteria in Section 3.4.3.6 are satisfied.

7. The staff reviews the narrative and tabular summary of the results of the ISA to determine if the information provided is complete and satisfies the acceptance criteria in Section 3.4.3.7 and Appendix A. The information reviewed includes:

a. a listing of hazardous materials and conditions and a table showing interactions between materials and between materials and conditions that could result in a hazardous situation; and

b. either:
(i) A tabular summary listing of each accident sequence that could result in radiological or chemical exposures to workers or the public, or environmental consequences. This tabular summary identifies for each sequence, the events that occur, including initiating event, and failures of safety controls, and the unmitigated consequences resulting. Staff reviews this list following the procedures in Appendix A; or, (ii) a set of logic diagrams that identify the all combinations and sequences of failure events that would cause consequences of concern.

8. The staff reviews the tabular list describing the administrative and engineered safety controls identified in the accident sequences as being relied on for safety. The review determines if the controls satisfy the acceptance criteria provided in Section 3.4.3.8 and its appendix. These criteria specify the redundancy, independence, quality, and reliability of the controls needed to assure that the likelihood and consequences of identified accidents meet the safety performance requirements of 10 CFR 70.61.

The risk significance of accident sequences will be evaluated by staff using the risk indices from Table A-1 in Appendix A. The procedure for evaluating risk significance is described in the last section of Appendix A. Accident sequences will be placed in categories. Safety controls appearing in those sequences in the category of highest risk significance will each be reviewed in detail. Independent evaluation or site visits will be performed, if warranted. For accident sequences categorized as lower risk significance, staff will select a representative sample (e.g., 5 to 10%) of sequences for specific evaluation, while the remainder receive a less detailed review.

9. The staff reviews the management practices proposed by the applicant to ensure that the ISA is used so as to assure safety, and is kept current and accurate. The reviewer verifies that the applicant practices mandate adequate procedures for ISA performance, update, review responsibility, documentation, and record maintenance.

3.6 EVALUATION FINDINGS

The reviewer verifies that the information submitted by the applicant is sufficiently complete so that compliance with 10 CFR Part 70 can be evaluated. The reviewer also verifies that the applicant's submittal contains sufficient information and that the staff review supports statements and conclusions of the following type, which the staff should include in the SER:

Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals associated with licensed materials. The applicant has performed an Integrated Safety Analysis (ISA) to identify and evaluate those hazards and potential accidents, and to establish safety controls to ensure facility operation within the bounds of the ISA. The NRC staff has reviewed those postulated accidents resulting from the facility hazards that may be anticipated to occur (or are considered unlikely or highly unlikely). To ensure that the limits in 10

CFR Part 70 are met, the applicant has adequately established both administrative and engineered safety controls. The staff has reviewed these safety controls and finds them acceptable based on the ISA evaluation and other supporting information.

The staff concludes that (1) the identification and evaluation of the hazards and accidents as part of the ISA and (2) the establishment of controls to maintain safe facility operation from their consequences meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public will be adequately protected.

3.7 REFERENCES

AIChE, *Guidelines for Hazard Evaluation Procedures*, *Second Edition with Worked Examples*, American Institute of Chemical Engineers, New York, September 1992.

American National Standards Institute, ANSI/ANS-8.1-1983, "Nuclear Criticality Safety in Operations With Fissionable Materials Outside Reactors," American Nuclear Society, La Grange Park, IL, 1983.

American National Standards Institute, ANSI/ANS-51.1-1983, "Nuclear Safety Criteria for the Design of Stationary Pressurized Water Reactor Plants," American Nuclear Society, La Grange Park, IL, 1983.

Code of Federal Regulations , Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

NUREG-1513, *Integrated Safety Analysis Guidance Document*, 1995.

U.S. Dept. of Commerce, Bureau of the Census, Statistical Abstract of the United States 1995, Table No. 688.

APPENDIX A

EXAMPLE PROCEDURE FOR RISK EVALUATION

NRC requirements in 10 CFR 70.61 require that the occurrence of consequences of concern, defined in 70.61, be sufficiently unlikely. In addition, 10 CFR 70.62(c) requires that the applicant perform an ISA to identify all potential accident sequences and to assess their consequences. These two requirements are related. The consequences of concern result from accident sequences identified in the ISA. Thus, to show that the likelihood of occurrence of the consequences is sufficiently low, it is necessary to show that for each of the accident sequences identified in the ISA, the resulting consequences are sufficiently unlikely.

As defined in 10 CFR 70.61, the required likelihood is graded according to the severity of the consequences of the accident. Accidents in the intermediate consequence category of 70.61(c) must be "unlikely", while those in the high consequence category of 70.61(b) must be "highly unlikely". The procedure described in this appendix is one way by which the applicant may use the ISA results to demonstrate that the requirements of 10 CFR 70.61 have been met. If the licensee evaluates accidents using a different method, the method should produce similar results in terms of how accidents are categorized. This method should be regarded as a screening method, not as a definitive method of proving the adequacy or inadequacy of the controls for any particular accident. The method requires the licensee to identify and evaluate the characteristics of controls used to limit accident sequences in a consistent manner. This will permit identification of accident sequences with defects in the combination of controls used. Such controls can then be further evaluated or improved to establish adequacy. The procedure also ensures the consistent evaluation of similar controls by different ISA teams. Sequences or controls that have risk significance, and are evaluated as marginally acceptable, are good candidates for more detailed evaluation by the applicant and the reviewer.

The tabular accident summary resulting from the ISA should identify, for each sequence, what safety controls must fail for consequences of concern in 10 CFR 70.61 to occur. Section 3.4.3.8 specifies acceptance criteria for these safety controls, such that the performance requirements of 70.61 are met. These criteria require that safety controls be sufficiently unlikely to fail. However, the criteria of 3.4.3.8 do not provide for a method for assessing likelihood. This appendix describes an acceptable procedure for this required assessment of likelihood.

A.1 DETERMINING COMPLIANCE WITH GRADED PROTECTION REQUIREMENTS

Section 70.61 of 10 CFR Part 70 describes requirements for a graded system of protection sufficient to bound the risk of identified accidents by making accidents of higher potential consequences have a proportionately lower likelihood of occurrence. The regulation specifies two categories of consequences of concern into which an accident may fall. The first category is referred to in 70.61 as "high consequences", the second as "intermediate consequences". Implicitly there is a third category; namely, those accidents that produce consequences less than "intermediate". These will be referred to as "low consequence" accidents. Since the primary purpose of Process Hazard Analysis is to identify all accidents having consequences of concern, it will, in some cases, be necessary to identify accidents that produce radioactive

or chemical exposures, then subsequently determine that some of these exceed the threshold values of the regulation. For this reason, the list of accidents resulting from such analysis will include such low consequence accidents in order to show that they have been considered. Otherwise, the analysis will not have demonstrated its completeness.

The limits defining the three accident consequence categories are given below. Note that the categories are numbered in ascending order of the magnitude of their consequences. The usefulness of this numbering will be evident later. The symbols AEGL and ERPG refer to chemical exposure levels from accidents sufficient to produce certain effects. AEGL-3 and ERPG-3 levels are life threatening.

Consequence Category 3- High Consequences: An accident resulting in any consequence specified in 70.61(b); that is: an acute worker exposure of 1 Sievert (100 rem)[4] or greater TEDE*, or a chemical exposure that could endanger the life of a worker (above AEGL-3 or ERPG-3); or acute exposure of a member of the public outside the controlled area to a radiation dose of 0.25 Sievert (25 rem) or greater TEDE, a 30 mg soluble uranium intake, or a chemical exposure that could lead to irreversible or other serious long-lasting health effects (exceeding AEGL-2 or ERPG-2).

Consequence Category 2- Intermediate Consequences: An accident resulting in any consequence specified in 70.61(c). That is, acute exposure of a worker to a radiation dose between 0.25 Sievert and 1 Sievert TEDE, or chemical exposure that could lead to irreversible or other serious long-lasting health effects (above AEGL-2 or ERPG-2); or acute exposure of a member of the public outside the controlled area to a radiation dose between 0.05 and 0.25 Sievert TEDE, or a chemical exposure that could cause mild transient health effects (exceeding AEGL-1 or ERPG-1); or prompt release of radiation outside the restricted area that would, if averaged over a 24 hour period, exceed 5000 times the values specified in Table 2 of Appendix B to 10 CFR Part 20.

Consequence Category 1- Low Consequences: Any accident with potential adverse radiological or chemical consequences but at exposures less than Categories 3 and 2 above.

* TEDE is Total Effective Dose Equivalent (see 10 CFR Part 20)

This system of consequence categories is shown in the following table. In the table, D signifies the TEDE from an acute accidental radiation exposure.

[4]A nuclear criticality would normally be considered a high consequence event because of the potential for producing a high radiation dose to a worker.

CONSEQUENCE SEVERITY CATEGORIES BASED ON 10 CFR 70.61

	Workers	Offsite Public	Environment
Consequence Category 3: high	D>1 Sv (100 rem) >AEGL3, ERPG3	D>.25 Sv (25 rem) 30 mg sol U intake >AEGL2, ERPG2	
Consequence Category 2: intermediate	.25 Sv<D# 1 Sv >AEGL2, ERPG2 but <AEGL3, ERPG3	.05 Sv<D# .25 Sv >AEGL1, ERPG1 but <AEGL2, ERPG2	radioactive release >5000 x Table 2 App B 10 CFR 20
Consequence Category 1: low	accidents of lesser radiological and chemical exposures to workers than those above in this column	accidents of lesser radiological and chemical exposures to the public than those above in this column	radioactive releases producing effects less than those specified above in this column

Corresponding to the two consequence categories of the rule (Categories 2 and 3 above), 70.61 requires corresponding levels of graded protection, that is, safety controls and management measures, sufficient to ensure that the likelihood of these adverse events is correspondingly low. The two categories of likelihood thus prescribed are:

Likelihood Category 1: Consequence Category 3 accidents must be “highly unlikely”, and

Likelihood Category 2: Consequence Category 2 accidents must be “unlikely.”

Implicitly there is a third category into which an accident could fall, that is it could fail to be “unlikely.” This category will be referred to in this document as:

Likelihood Category 3: “not unlikely.”

Although this category includes unintended events that might actually be expected to happen, others might be less frequent. For this reason the term “likely” was not used for these events.

A major purpose of the ISA is to show compliance with the above system of graded protection. This can be done by using the required tabular summary of identified accident sequences. One acceptable way of doing so is for the applicant to assign two category numbers to each accident sequence, one based on its consequences and one for likelihood. The product of these two category numbers is then used as a risk index. Listing this calculated risk index in the tabular summary provides a simple method for showing that the graded protection requirements have been met for each accident sequence. A risk index value less than or equal to “4" means the sequence is acceptable. If the applicant provides this risk index in one column of the tabular summary, the reviewer can quickly scan this column to confirm that each

accident conforms to the safety performance requirements of 10 CFR 70.61. This system is equivalent to assigning each accident to a cell in a 3 by 3 matrix. This conceptual matrix is shown below. The values in the matrix cells are the risk index numbers.

RISK MATRIX

	Likelihood Category 1: highly unlikely	Likelihood Category 2: unlikely	Likelihood Category 3: not unlikely
Consequence Cat. 3 High	3 acceptable	6 unacceptable	9 unacceptable
Consequence Cat. 2 Intermediate	2 acceptable	4 acceptable	6 unacceptable
Consequence Cat. 1 Low	1 acceptable	2 acceptable	3 acceptable

To demonstrate compliance with the system described above, the applicant needs to assign consequence categories to each identified accident in order to determine which likelihood requirement applies. Then those accident sequences identified as high or intermediate consequences must be assigned to a likelihood category. To be acceptable, these assigned consequences and likelihoods must have a valid basis, and the applicant must demonstrate this basis in the documentation submitted in the application. The following sections describe an acceptable method for making these assignments.

A.2 CONSEQUENCE CATEGORY ASSIGNMENT

The assignment of consequence categories is based on estimated consequences of prototype accidents. Criteria for the presentation of these estimates by the applicant is described in Section 3.4.3.7. Although consequences of accidents can be determined by actual calculations, it is not necessary that such a calculation be performed for each individual accident sequence listed. Accident consequences may be estimated by comparison to similar events for which reasonably bounding conservative calculations have been made. The applicant should document the bases for bounding calculations of the consequence assignment in the submittal. NUREG/CR-6410, Nuclear Fuel Cycle Facility Accident Analysis Handbook, describes valid methods and data to be used by the applicant and may be used for confirmatory evaluations by the reviewer.

A.3 LIKELIHOOD CATEGORY ASSIGNMENT

An assignment of an accident sequence to a likelihood category is acceptable if it is based on the record of failures at the facility or other methods that have objective validity. Because sequences leading to accidents often involve multiple failures, a combination of failure frequency and probability values determines the likelihood of the whole sequence. These values include the frequencies of initiating events and failure likelihoods of safety controls. An

acceptable method is described below by which the applicant can make an estimate of an approximate likelihood category for an accident sequence by considering all the events involved. This method makes use of the number, type, independence, and observed failure history of safety controls. However a correct evaluation of the appropriate likelihood of accidents using such a qualitative system depends on the informed judgement of the analyst. Safety controls, even those of the same types, have a wide range of reliability. The ultimate criterion for acceptability, is that the frequencies of initiating events and the likelihood of failure of safety controls involved is sufficiently low so that the entire accident sequence is "highly unlikely" or "unlikely" as required by 10 CFR 70.61. The virtue of the structure is that it requires explicit consideration of some of the underlying events and factors that affect the likelihood of the accident. Another virtue is that, the more explicit the criteria for assignment are, the more consistent are the results.

Underlying any evaluation of an accident sequence as "unlikely" or "highly unlikely" is an implied assessment of its "likelihood" or frequency of occurrence. The structured procedure described below will indicate which likelihood category may be appropriate for an event. In order to maintain internal consistency in evaluating different control systems and accidents, it was necessary to derive this structured procedure based on the underlying frequencies of events. The following numerical guidelines were thus used to obtain consistency:

Likelihood Category 1: highly unlikely, a frequency of less than 10^{-5} per accident per year

Likelihood Category 2: unlikely, a frequency of less than 10^{-2} per accident per year (but more frequent than 10^{-5})

Likelihood Category 3: not unlikely, more frequent than 10^{-2} per accident per year

In assessing the adequacy of safety controls, individual accidents frequencies greater than 10^{-5} per year may not be "highly unlikely". The NRC has a strategic safety performance measure of no inadvertent nuclear criticalities. For this reason, the acceptability of any given frequency depends on the total number of accidents that may be identified. Since the total number and consequences of all potential accidents at a facility is not accurately known until its ISA is completed, it is difficult to establish a definitive acceptable frequency. Individual accidents may need to be limited to lower values in order to achieve an overall acceptable risk. On the other hand, the fact that a particular accident sequence is below this value does not automatically mean that it is clearly acceptable. The frequency value is to be used as a guideline in developing more consistent and objective standards for safety control features. The value of 10^{-5} per year per accident is such that a plant with 100 potential Consequence Category 3 accidents would have a frequency of: 100 accidents times 10^{-5} per year per accident = 10^{-3} per year. These Category 3 accidents generally result in fatalities. The average statistic for all manufacturing industries is that a plant with 250 manufacturing workers would expect 10^{-2} on-the-job deaths per year (see References, Statistical Abstract of the U.S.).

Similarly, accident sequences having frequencies more than 10^{-2} per year per accident are not considered "unlikely." Again this value should not be taken as a definitive criterion for acceptability. It is a guideline value to assure consistency. It may need to be adjusted based on the numbers and severity of accidents. The rationale for the value 10^{-2} is that accidents of

the corresponding severity, Consequence Category 2, are not common and should remain so. To achieve this, the product of this frequency per accident per year with the assessed number of potential accidents should provide adequate confidence that such accidents will not occur. Note again that these values of 10^{-5} and 10^{-2} are per accident per year.

The accident evaluation method described below does not preclude the need to comply with the double contingency principle for sequences leading to criticality. Although exceptions are permitted with compensatory measures, double contingency, should, in general, be applied. The reason double contingency is needed is the fact that there is usually insufficient firm data as to the reliability of the control equipment and administrative control procedures used in criticality safety. If only one item were relied on to prevent a criticality, and it proved to be less reliable than expected, then the first time it failed a criticality accident would result. For this reason, it is prudent to require two independent controls. Inadequate controls can then be determined by observing their failure, without also suffering the consequence of a criticality. Even with double contingency it is essential that each item relied on for safety be itself sufficiently unlikely to fail. This is so that, if one of the two items that establish double contingency is actually ineffective, criticality will still be unlikely.

A.4 RISK INDEX EVALUATION SUMMARY

As previously mentioned, an acceptable way for the applicant to present the results of the ISA is a tabular summary of the identified accident sequences. Table A-1 is an acceptable format for such a table. This table lists several example accident sequences for a powder blender at a typical facility. Table A-1 summarizes two sets of information: (1) the accident sequences identified in the ISA, and (2) a risk index calculated for each sequence to show compliance with the regulation. A summary of the risk index calculation will be given below.

Accident sequences result from initiating events, followed by failure of one or more controls. Thus there are columns in Table A-1 for the initiating event and for controls. Controls may be mitigative or preventive. Mitigative controls are measures that reduce the consequences of an accident. The phrase “unmitigated consequences” describes the results when the system of preventive controls fails and mitigation also fails. Mitigated consequences result when the preventive controls fail, but mitigative measures succeed. These are abbreviated in the table as “unmit.” and “mitig.”, respectively. Index numbers are assigned to initiating events, control failure events, and mitigation failure events, based on the reliability characteristics of these items.

With redundant safety controls and in certain other cases, there are sequences where an initiating event occurs that places the system in a vulnerable state. While the system is in this vulnerable state, a safety control must fail in order for the accident to result. Thus the frequency of the accident depends on the frequency of the first event, the duration of vulnerability, and the frequency of the (second) control failure. For this reason, it is necessary to consider the duration of the vulnerable state, and to assign it a duration index. The values of all index numbers for a sequence, depending on the number of events involved, are added to obtain a total likelihood index, T. Sequences are then assigned to one of the three likelihood categories of the Risk Matrix depending on the value of this index in accordance with Table A-2.

The values of index numbers in sequences are assigned considering the criteria in Tables A-3 through A-5. Each table applies to a different type of event. Table A-3 applies to events which have frequencies of occurrence, such as initiating events and certain control failures. When failure probabilities are required for the event, Table A-4 provides the index values. Table A-5 provides index numbers for durations of failure. These are used in certain accident sequences where two controls must simultaneously be in a failed state. In this case, one of the two controlled parameters will fail first. It is then necessary to consider the duration that the system remains susceptible to failure of the second. The reverse sequence, where the second control fails first, should also be considered as a separate accident sequence. This is necessary because the duration of failure of the second control will usually differ from that of the first. The values of these duration indices are not merely judgmental. They are directly related to the time interval of surveillance monitoring for failures. That is, the duration of a failure is the time until it is detected plus the time to restore the system to a state where it is not vulnerable to the second failure.

For all these index numbers, the more negative the number is, the less likely is the failure. Accident sequences may consist of varying numbers of events, starting with an initiating event. The total likelihood index is the sum of the indices for all the events in the sequence, including those for duration.

Consequences are assigned to one of the three consequence categories of the Risk Matrix based on calculations or estimates of the actual consequences of the accident sequence. The consequences of concern are those of 10 CFR 70.61. Multiple types of consequences can result from the same event. The consequence category is chosen for the most severe consequence.

As shown in the first row of Table A-1, the failure duration index can make a large contribution to the total likelihood index. Therefore, the reviewer should verify that there is adequate justification that the failure will be corrected in the time ascribed to the duration index. In general, duration indices with values less than minus one (-1), corresponding to 36 days, to be acceptable, should be based on the existence of intentional monitoring of the process. The duration of failure for an unmonitored process should be conservatively estimated.

Table A-1 provides two risk indices for each sequence in order to permit evaluation of the risk significance of the controls involved. To measure whether a control has high risk significance, the Table provides an “uncontrolled risk index”, determined by modeling the sequence with all controls as failed (i.e., not contributing to a lower likelihood). In addition, a “controlled risk index” is also calculated, taking credit for the low likelihood and duration of control failures. When an accident sequence has an uncontrolled risk index exceeding 4, but a controlled index of less than 4, then the safety controls involved have a high risk significance in that they are relied on to achieve acceptable safety performance. Thus use of these indices permits evaluation of the possible benefit of improving controls, and also where a relaxation may be acceptable.

Table A-6 provides a more detailed description of the accident sequences used in the example of Table A-1. The reviewer needs the information in Table A-6 to understand the nature of the accident sequences listed in Table A-1. Table A-1 lacks sufficient room to explain any but the simplest failure events.

Table A-7 is used to explain the safety controls and external initiating events that appear in the accident sequences in Table A-1. The reviewer needs the information in Table A-7 to understand why the initiating events and safety controls listed in Table A-1 have the low likelihood indices assigned. Thus Table A-7 needs to address such information as: the margins to safety limits, the redundancy of a control, the measures taken to assure adequate reliability of a control. Table A-7 must also justify why those external events, which are not obviously extremely unlikely, have the low likelihoods which are being relied on for safety. The applicant should provide separate tables to list the controls for criticality, chemical, fire, radiological, and environmental accidents.

Definitions and explanations of the terms used in the following tables will follow the last table.

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TABLE A-1: EXAMPLE ACCIDENT SEQUENCE SUMMARY AND RISK INDEX ASSIGNMENT

Process: UO2 Powder Preparation (PP) Unit Process: Additive Blending Node: Blender Hopper Node (PPB2)

Accident Sequence	Initiating Event (a)	Preventive Control 1 (b)	Preventive Control 2 (c)	Mitigation Control (d)	Likelihood* Index T (e) uncontrolled controlled	Likelihood Category (f)	Consequence Evaluation Reference	Consequence Category (g)	Risk Indices (h=f x g) uncontrolled controlled	Comments & Recommendations
PPB2-1A (Criticality from blender leak of UO_2)	see Control 1 (note 1)	PPB2-C1: Mass Control Failure: Blender leaks UO_2 onto floor, critical mass exceeded frq1 = -1 dur1 = -4	PPB2-C2: Moderation Failure: Suffic. water for criticality introduced while UO_2 on floor frq2 = -2	N/A	unc T = -1 con T = -7	unc 3 con 1	rad 35	3 (crit: 3, rad: 0)	9 3	criticality, consequences = 3 Control 2 fails while Control 1 is in failed state. T = -1-4-2 = -7
PPB2-1B (Rad. release from blender leak of UO_2)	blender leaks UO2 frqi = -1	PPB2-C1: Mass Control success: leaked UO_2 below critical mass, OR	PPB2-C2: Moderation success: no moderator	Ventilation Failure: Ventilated blender enclosure frqm = -2	unc T = -1 con T = -3 con T = -1	unc 3 unmit. 2 mitig. 3	rad 36	unc 2 unmit. 2 mitig. 1	6 unmit. 4 mitig. 3	rad consequences, no criticality unmitigated sequence: control 1 & mitigation fail. T= -1-2 = -3 mitig.: Control 1 fails, mitig. control does not fail. T = -1
PPB2-1C	see Control 1 (note 1)	PPB2-C2: Moderation Failure: Suffic. water for criticality on floor under UO_2 blender frq1 = -2 dur1 = -3	PPB2-C1: Mass Control Failure: Blender leaks UO_2 on floor while water present frq2 = -1	N/A	unc T = -2 con T = -6	unc 2 con 1	rad 35	3 (crit: 3, rad: 0)	6 3	criticality by reverse sequence of PPB2-1A, moderation fails first. Note different likelihood T = -6
PPB2-2	Fire in Blender Room frqi = -2	Fire Suppression Failure: Fails on demand: prf1 = -1	N/A	N/A	unc T = -2 con T = -3	unc 2 con 2	rad 37	2 (rad) 1	4 2	Event sequence is just initiating event plus one control failure on demand

*Likelihood index T is a sum. uncontrolled: T=frqi or frq1; controlled: includes all indices T=a+b+c+d

Note 1: For these sequences the initiating event is failure of one of the controls, hence the frequency is assigned under that control.

TABLE A-2: DETERMINATION OF LIKELIHOOD CATEGORY

LIKELIHOOD CATEGORY	LIKELIHOOD INDEX T (= sum of index numbers)
1	T # -5
2	-5 < T # -2
3	-2 < T

TABLE A-3: FAILURE FREQUENCY INDEX NUMBERS

FREQUENCY INDEX NUMBER	BASED ON EVIDENCE	BASED ON TYPE OF CONTROL**	COMMENTS
-6 *	external event with freq. < 10^{-6} /yr		If initiating event, no controls needed
-4 *	no failures in 30 yrs for hundreds of similar controls in industry	exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 independent AEC, PEC, or enhanced admin. controls	rarely can be justified by evidence, since few systems are found in such large numbers. Further, most types of single control have been observed to fail.
-3 *	no failures in 30 years for tens of similar controls in industry	a single control with redundant parts, each a PEC or AEC	
-2 *	no failure of this type in this plant in 30 years	a single PEC	
-1	a few failures may occur during plant lifetime	a single AEC, an enhanced administrative control, an admin. control with large margin, or a redundant admin. control	
0	failures occur every 1 - 3 years	a single administrative control	
1	several occurrences per year	a frequent event	not for safety controls, just initiating events
2	occurs every week or more often	frequent event, an inadequate control	not for safety controls, just initiating events

* Indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other management measures are of high quality, because, without these measures, the controls may be changed or not maintained.

** The index value assigned to a control of a given type in column 3 may be one value higher or lower than the value given in column 1. Criteria justifying assignment of the lower (more negative) value should be given in the narrative describing ISA methods. Exceptions require individual justification.

TABLE A-4: FAILURE PROBABILITY INDEX NUMBERS

PROBABILITY INDEX NUMBER	PROBABILITY OF FAILURE ON DEMAND	BASED ON TYPE OF CONTROL	COMMENTS
-6 *	10^{-6}		If initiating event, no controls needed
-4 or -5*	10^{-4} - 10^{-5}	exceptionally robust passive engineered control (PEC), or an inherently safe process, or 2 redundant controls better than simple admin controls (AEC, PEC, or enhanced admin)	rarely can be justified by evidence, since few systems are found in such large numbers . Further, most types of single control have been observed to fail.
-3 or -4*	10^{-3} - 10^{-4}	a single passive engineered ctrl. (PEC) or an active engineered control (AEC) with high availability	
-2 or -3 *	10^{-2} - 10^{-3}	a single active engineered control, or an enhanced admin control, or an admin control for routine planned operations	
-1 or -2	10^{-1} - 10^{-2}	an admin control that must be performed in response to a rare unplanned demand	

* Indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other management measures are of high quality, because, without these measures, the controls may be changed or not maintained.

TABLE A-5: FAILURE DURATION INDEX NUMBERS

DURATION INDEX NUMBER	AVG. FAILURE DURATION	DURATION IN YEARS	COMMENTS
1	more than 3 years	10	
0	one year	1	
-1	one month	0.1	Formal monitoring to justify indices less than “-1"
-2	a few days	0.01	
-3	8 hours	0.001	
-4	1 hour	10^{-4}	
-5	5 minutes	10^{-5}	

TABLE A-6: ACCIDENT SEQUENCE DESCRIPTIONS

Process: UO2 Powder Preparation (PP) Unit Process: Additive Blending
Node: Blender Hopper Node (PPB2)

Accident Sequence (see Table A-1)	DESCRIPTION
PPB2-1A Blender UO_2 leak criticality	The initial failure is a blender leak of UO_2 that results in a mass sufficient for criticality on the floor. (This event is not a small leak.) Before UO_2 can be removed, moderator sufficient to cause criticality is introduced. Duration of critical mass UO_2 on floor estimated to be one hour.
PPB2-1B Blender UO_2 leak, rad. release	The initial failure is a blender leak of UO_2 that results in a mass insufficient for criticality on the floor, or mass sufficient for criticality but moderation failure does not occur. Consequences are radiological, not a criticality. A ventilated enclosure should mitigate the radiological release of UO_2. If it fails during cleanup or is not working, unmitigated consequences occur.
PPB2-1C	The events of PPB2-1A occur in reverse sequence. The initial failure is introduction of water onto the floor under the blender. Duration of this flooded condition is 8 hours. During this time, blender leaks a critical mass of UO_2 onto the floor. Criticality occurs.
PPB2-2	Initiating event is a fire in the blender room. Fire is not extinguished in time. Release of UO_2 from process equipment occurs. Offsite dose estimated to exceed 100 mrem.

TABLE A-7: CRITICALITY SAFETY LIMITS AND CONTROLS

Process: UO2 Powder Preparation (PP) Unit Process: Additive Blending
Node: Blender Hopper Node (PPB2)

Safety Control Identifier	Safety Parameter and Limits	Safety Controls Description	max value of other parameters	Reliability Management measures	QA Grade
PPB2-C1	Mass Outside Hopper: zero	Mass Outside Hopper: Hopper and outlet design prevent UO_2 leaks, double gasket at outlet.	Full Water Reflection, Enrichment 5%	surveillance for leaked UO2 each shift	A
PPB2-C2	Moderation: in UO_2 < 1.5 wt. % External Water in area: zero	Moderation In UO_2 : Two sample measurements by two persons before transfer to hopper. External Water: Posting excluding water, double piping in room, floor drains, roof integrity	Full Water Reflection, Enrichment 5%	drain, roof, and piping are under safety grade maintenance	A

Note: In addition to engineered controls, this table should include descriptions of external initiating events whose low likelihood is relied on to achieve acceptable risk, especially those which are assigned frequency indices lower than -4. The descriptions of these initiating events should contain information supporting the frequency index value selected by the applicant.

ACCIDENT SUMMARY AND RISK INDEX ASSIGNMENT FOR TABLE A-1

The definitions for the contents of each column in the accident summary tabulation, Table A-1, are provided below.

Accident Sequence

This column is provided to list the accident sequences identified by the applicant in the ISA. It is important to the proper documentation of the ISA that the applicant subdivides the plant into a set of uniquely identified units, referred to here as "nodes". The applicant should give symbols, names, or numbers to these nodes that permit them to be uniquely identified. For example, the "Blender Hopper" node described In Table A-1 has the unique identifying symbol PPB2. Additional identifier characters have been added to form the identifier, PPB2-1, to identify the first accident sequence identified in that node. Because the applicant should list all the plant safety controls of significance used elsewhere in the ISA, tabulations of the unique node (and accident) identifier can be used to find the accidents that these safety controls have been shown to prevent. By reviewing this table, the reviewer can then evaluate (1) the adequacy of the controls for preventing accidents and (2) the bases for making the consequence and likelihood assignments in the table.

Initiating Event or Control Failure

This column is provided to list initiating events or control failures, typically identified in the Process Hazard Analysis phase of the ISA, that may lead to consequences of concern. Initiating events are of several distinct types: (1) external events, such as hurricanes and earthquakes, (2) plant events external to the node being analyzed (e.g., fires, explosions, failures of other equipment, flooding from plant water sources), (3) deviations from normal of the process in the node (i.e., credible abnormal events), and (4) failures of safety controls of the node. The tabulated initiating events should only consist of those that involve an actual or threatened failure of safety controls, or that cause a demand requiring controls to function in order to prevent consequences of concern. The frequency index number for initiating events is referred to in the table using the symbol "frqi". Table A-3 provides criteria for assigning a value to frqi. Usually, insufficient room is present in a tabular presentation like Table A-1 to describe accurately the events indicated. Consequently, the applicant should provide supplementary narrative information to adequately describe each accident sequence of Table A-1. Cross referencing between this information and the table should be adequate, for instance, the unique symbolic accident sequence identifiers can be used. Table A-6 is an example of a list of supplementary accident sequence descriptions corresponding to Table A-1.

Preventive Control 1

This column is provided to list a control designed to prevent consequences of concern. If separate controls are used to prevent different consequences, separate rows in the table should be defined corresponding to each type of consequence. Table A-1 contains an example of a set of related sequences so separated. Sequences where two controls must simultaneously be in a failed state require assignment of three index numbers: the failure frequency of the first control, frq1, the duration of this failure, dur1, and the failure frequency of the second control, frq2. For such sequences, the initiating event is failure of the first control. In these cases, frq1 is assigned using Table A-3. The failure duration of the first control is assigned using Table A-5. Other sequences may be more easily described as a failure of the safety controls on demand after the occurrence of an initiating event. In these cases, the failure probability index number, prf1, is assigned using Table A-4. The symbol "b" is used in the column heading for the indices associated with this control.

Preventive Control 2

This column is provided in case a second preventive control exists. The failure frequency or failure probability on demand is assigned as for Preventive Control 1. The symbol “c” is used in the column heading for the indices associated with this control.

Mitigation Control

This column is provided in case controls are available to mitigate the accident. That is, they reduce, but do not eliminate, the consequences of a sequence. A control that eliminates all adverse consequences should be considered preventive. The symbol “d” is used in the column heading for the indices associated with this control.

Likelihood Category

This column is provided to list the likelihood category number for the risk matrix, which is based on the total likelihood index for a sequence. The total likelihood index, T, is the sum of the indices for those events that comprise a sequence. These events normally consist of the initiating event, and failure of one or more controls, including any failure duration indices. However, accident sequences may consist of varying numbers and types of undesired events. Methods for deciding what frequencies and failure durations need to be considered will be described later in this appendix. Based on the sum of these indices, the likelihood category number for the risk matrix is assigned using Table A-2. The symbol “e” is used for this category number in the column heading.

Consequence Evaluation Reference

This column permits identification of the consequence calculations that relate to this accident sequence. Multiple references may be required to refer to calculations of the different types of consequences, radiological, various chemicals, etc..

Consequence Category

This column is provided to assign the consequence category numbers based on estimating the consequences of all types (i.e., radiological, criticality, chemical, and environmental) that may occur. Based on this estimate, accidents can be assigned to the categories defined in 10 CFR 70.61. The symbol “f” is used for this category number in the column heading. Sequences having controls to mitigate consequences must be divided into two cases, one where the mitigation succeeds, and one where it fails, each with different consequences. The two cases may be tabulated in one row of Table A-1, but the mitigated and unmitigated consequences should be separately indicated. Unless the mitigated case results in consequences below those of concern in 10 CFR 70.61, both cases must satisfy the likelihood requirements as shown by the risk matrix.

Risk Index

This column is provided to list the risk index, which is calculated as the product of the likelihood category and consequence category numbers. This is shown in the column heading by the formula “g = e x f”. Sequences with values of “g” less than or equal to “4" are acceptable. Another risk index can also be calculated as the product of the consequence category number times the likelihood category associated with only the failure frequency index for the initiating event. The resulting product can be referred to as the “unmitigated” risk index. It is unmitigated in the sense that no credit is taken for the functioning of any subsequent controls. For example, in the first three cases in Table A-1, the initiating event is failure of Preventive Control 1. In these cases, the failure frequency of Preventive Control 1 is used to determine the likelihood category when calculating the unmitigated risk index.

Comments and Recommendations

This column is needed to record ISA team recommendations, especially when the existing system of controls is evaluated as being deficient. This may happen because a newly identified accident sequence is not addressed by existing controls, or because a deficiency has been found in the existing controls.

DETERMINATION OF LIKELIHOOD CATEGORY IN TABLE A-2

The likelihood category is determined by calculating the likelihood index, T, then using this table. The term T is calculated as the sum of the indices for the events in the accident sequence.

DETERMINATION OF FAILURE FREQUENCY INDEX NUMBERS IN TABLE A-3

Table A-3 is used to assign frequency index numbers to plant initiating events and control system failures as found in the columns of Table A-1. The term failure must be understood to mean not merely failure of the control device or procedure, but also as violation of the safety limit by the process. In the example in Table A-1, accident sequence PPB2-1A involves loss of mass control over UO_2 in a blender. If criticality is the concern, failure does not occur unless UO_2 accumulates to a critical mass before the leak is stopped. For radiological consequences, any amount leaked may cause exposure. In assessing the frequency index, this factor should be considered because many control failures do not cause safety limits to be exceeded.

Table A-3 provides two columns with two sets of criteria for assigning an index value, one based on type of control, the other directly on observed failure frequencies. The types of controls are administrative, active engineered, passive engineered, etc. Since controls of a given type have a wide range of failure frequencies, assignment of index values based on this table should be done with caution. Due consideration should be given as to whether the control will actually achieve the corresponding failure frequency in the next column. Based on operational experience, more refined criteria for judging failure frequencies may be developed by an individual applicant. In the column labeled “Based on Type of Control”, references to redundancy allow for controls that may themselves have internal redundancy to achieve a necessary level of reliability.

Another objective basis for assignment of an index value is actual observations of failure events. These actual events may have occurred in the applicant plant or in a comparable process elsewhere. Justification for specific assignments may be noted in the Comments column of Table A-1.

As previously noted, the definition of failure of a safety control to be used in assigning indices is, for non-redundant controls, a failure severe enough to cause an accident with consequences. For redundant controls, it is a failure such that, if no credit is taken for functionality of the other control, an accident with consequences would result. If most control malfunctions would qualify as such failures, then the index assignments of this table are appropriate. If true failure is substantially less frequent, then credit should be taken and adequate justification provided.

Note that indices less than (more negative than) “-1" should not be assigned to controls unless the configuration management, auditing, and other required management measures are of high quality, because, without these measures, the controls may be changed or inadequately maintained. The reviewer should be able to determine this from a tabular summary of safety controls provided in the application. This summary should include identification of the process parameters to be controlled and their safety limits, and a thorough description of the control and its applied management measures.

DETERMINATION OF FAILURE PROBABILITY INDEX NUMBERS IN TABLE A-4

Occasionally, information concerning the reliability of a safety control may be available as a probability on demand. That is, a history may exist of tests or incidents where the system in question is demanded to function. To quantify such accident sequences it is necessary then to know the demand frequency, the initiating event, and the demand failure probability of the safety control. This table provides an assignment of index numbers for such controls in a way that is consistent with Table A-3. The probability of failure on demand may be the likelihood that it is in a failed state when demanded (availability), or that it fails to remain functional for a sufficient time to complete its mission.

DETERMINING MANAGEMENT MEASURES FOR SAFETY CONTROLS

Table A-7 is an acceptable way of listing those items relied on for safety in all the accident sequences leading to consequences of concern. The items listed should include all safety controls and all external events whose low likelihood is relied upon to meet the performance requirements of 10 CFR 70.61. Staff reviews this list to determine whether measures have been applied to each safety control adequate to assure their continual availability and reliability in conformance to 10 CFR 70.62(d). The types of management measures include maintenance, training, configuration management, audits and assessments, quality assurance, etc. These management measures are indicated in the Baseline Design Criteria and described in greater detail in Chapters 4 through 7 and Chapter 11. Safety controls meeting all the provisions of these chapters have acceptable management measures, that is, they comply with 70.62(d). Safety controls may, with justification, have lesser management measures than those described. However, every item relied on for safety in accident sequences leading to consequence categories 2 or 3 should be assigned at least a minimal set of management measures. Specifically, in order to defend against common mode failure of all controls on a process, this minimal set of measures must include an adequate degree of: a) configuration management, b) regular auditing for the continued effectiveness of the control, c) adequate labeling, training, or written procedures to assure the awareness of the operating staff of the safety function performed, d) surveillance and corrective maintenance, and e) preventive maintenance, if applicable.

If lesser or graded management measures are applied to some controls, Tables A-1 and A-7 and the narratives preceding them, in order to be acceptable, must identify to which controls these lesser measures are applied. In addition, information indicating that acceptable reliability can be achieved with these lesser measures must be presented. It is not necessary that the specifics of these measures, such as the surveillance interval, type of maintenance, or type of testing, be described as applied to each control. It is recognized that such specific measures must be applied differently to each control to whatever degree is necessary to achieve

adequate reliability. It is the formality, documentation, and QA requirements applied to these direct management measures that may be graded generically in a risk-informed manner.

The following describes the application of management measures to items relied on for safety based on the risk importance of the item in an accident sequence, as defined by (1) the "uncontrolled" risk index shown in Appendix A to this Chapter, and (2) the failure likelihood index, "T", also described in Appendix A. In summary, items relied on to prevent or mitigate accidents with unmitigated consequences in the two highest categories identified in 70.61 should satisfy the Baseline Design Requirements of 70.64 that apply.

1. For those sequences that are reduced in risk from initially high risk (an "uncontrolled" risk index of 6 or 9) to an acceptable risk ("controlled" risk index of less than or equal to 4):

   Items relied on for safety must have satisfied all applicable Baseline Design Requirements of Section 70.64.

2. For those sequences that are initially evaluated as being in an acceptable risk category (an "uncontrolled" risk index of less than or equal to 4):

   2A. If the initiating event is not a control failure, then assurances for items relied on for safety are not necessary. No additional risk reduction is required. However, for sequences claimed to be highly unlikely, the assessment that the initiating event has such a low frequency must be adequately justified in the application. Further, for accident sequences resulting in nuclear criticality, double contingency should still be achieved, thus requiring at least one more item relied on for safety, typically a control, in addition to the initiating event. This control must have satisfied all applicable Baseline Design Requirements of Section 70.64

   2B. If the initiating event is a control failure, and if the likelihood of that failure is taken to be at least a few times per plant lifetime (T is greater than -2), then assurances for that item relied on may be less than Baseline Design Requirements of 70.64, as defined by the applicant and approved by the NRC. Any subsequent items in the accident sequence will be unregulated.

   [Rationale: Since T is greater than -2, the likelihood category is 3. Therefore the consequence category is no greater than 1, to limit the uncontrolled risk index to at most 4. Since the consequence category is low, the assurance level can be reduced]

   2C. If the initiating event is a control failure, and if the likelihood of that failure is taken to be less than a few times per plant lifetime (T is less than or equal to -2), then assurance for this control must satisfy the full Baseline Design Requirements. No regulation of subsequent controls in the sequence is necessary.

   [Rationale: Since T is less than or equal to -2, the likelihood category must be 1 or 2. Therefore, the consequence category must be no greater than 2, in order to limit the uncontrolled risk index to at most 4. In this case, the uncertainty in determining a low failure likelihood requires compensatory measures in the form of increased assurances (high level criteria) that the control is indeed kept at a low failure likelihood]

RISK-INFORMED REVIEW OF SAFETY CONTROLS

Staff reviews the safety controls and external events listed in Table A-7 in a risk-informed manner as described in Section 3.5.8. The procedure for identifying systems of safety controls having higher risk significance is described in this section. These controls will be subject to a more detailed review by staff to assure their adequacy.

The final results column of Table A-1 gives the risk indices for each accident sequence that was identified in the ISA. There are two indices, uncontrolled and controlled. The controlled index is a measure of risk without credit for the safety controls. If the uncontrolled risk index is a 6 or 9, while the controlled index is an acceptable value (less than 5), the set of safety controls involved are significant in achieving acceptable risk. That is, these controls have high risk significance. The uncontrolled risk index will be used by staff to identify all risk significant sets of controls. These sets of controls will be reviewed with greater scrutiny than controls established to prevent or mitigate accident sequences of low risk.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

4.0 RADIATION SAFETY

4.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's radiation protection program is adequate to protect the radiological health and safety of workers and to comply with the regulatory requirements in 10 CFR Parts 19, 20, and 70. The content and level of detail in this chapter is more detailed because this chapter provides acceptance criteria for evaluating compliance with 10 CFR Part 20, which has very specific requirements. Review procedures and acceptance criteria for the applicant's program for protecting members of the public and the control of effluent releases is not included in this chapter, but is in Chapter 9, "Environmental Protection," of this SRP.

4.2 RESPONSIBILITY FOR REVIEW

Primary: Health Physicist

Secondary: Licensing Project Manager, Environmental Reviewer, and ISA Reviewer.

Supporting: Fuel Cycle Facility Inspector

4.3 AREAS OF REVIEW

A radiation protection program is required to be established and implemented per 10 CFR 20.1101. The areas of the radiation protection program that the staff will review include: As Low As Reasonably Achievable (ALARA), organizational relationships and personnel qualifications, radiation safety procedures and radiation work permits (RWPs), training, ventilation systems, air sampling, contamination control, external exposure, internal exposure, summing internal and external exposures, respiratory protection, and instrumentation. In addition to reviewing the radiation protection program, the staff will also review the radiation safety consequences to workers and associated items relied on for safety that are identified in the applicant's ISA summary and other ISA documentation as needed.

1. ALARA

   The staff will review the applicant's policy and procedures that are used to ensure that occupational radiological exposures are maintained ALARA including: (a) the organization structure and how units interact to maintain ALARA; (b) internal and external audits; (c) integration with the ISA; and (d) trend analysis to examine the historical patterns of exposures, concentrations of airborne radioactivity, contamination levels, instrumentation performance, respiratory protection equipment performance, and filter performance.

2. Organizational Relationships and Personnel Qualifications

The staff will review the applicant's organization of the radiological protection program, the qualification requirements for the radiological protection personnel, and the assignment of specific responsibilities and authorities for key functions.

3. Radiation Safety Procedures and Radiation Work Permits (RWPs)

The staff will review the applicant's commitments regarding the need for, the development and control of, and the use of approved written radiation safety procedures and RWPs for activities related to radiological safety.

4. Training

The staff will review the applicant's radiological safety training for all personnel who have authorized access to a restricted area. The review will include training objectives, management oversight, methodology of training, who receives the training, a description and the frequency of the training and refresher training, and the effectiveness of the training. Further aspects of training are covered in Section 11.3 of this SRP.

5. Ventilation Systems

The staff will review the applicant's requirements of and operation of the ventilation systems including the minimum flow velocity at hood openings, the types of filters and the maximum differential pressure across filters, and the frequency and types of tests required to measure ventilation system performance.

6. Air Sampling

The staff will review the applicant's radiological air sampling objectives and procedures, including: (a) the frequency and methods of analysis of airborne concentrations, (b) sampling methods and frequency, (c) counting techniques,
(d) lower limits of detection for specific radionuclides, (e) action levels and actions to be taken when the levels are exceeded, and (f) location of continuous air monitors (CAMs), if used, and annunciators and alarms associated with CAMs.

7. Contamination Control

The staff will review the applicant's control of radiological contamination within the facility including the types and frequencies of surveys, limits for contamination levels, the methods and choice of instruments used in the surveys, and the action levels and actions to be taken when the actions levels are exceeded. In addition, the staff will review the design features of the facility that control access including: (a) the types and availability of contamination monitoring equipment; (b) specific limits established for

personnel contamination; (c) minimum provisions for personnel decontamination; (d) minimum types of protective clothing necessary for individuals to enter restricted areas; (e) technical criteria and levels for defining contamination areas; (f) release criteria for radiological contaminated material, and (g) frequency of periodic reviews of all aspects of access control.

8. External Exposure

The staff will review the applicant's program for monitoring personnel external radiation exposure including the means to measure, assess, and record personnel exposure to radiation. In addition, the staff will review the type, range, sensitivity, accuracy, and frequency for analyzing personnel dosimeters and the action levels and actions to be taken when the actions levels are exceeded.

9. Internal Exposure

The staff will review the applicant's program for monitoring personnel internal radiation exposure, including: (a) the criteria for determining when it is necessary to monitor an individual's internal exposure; (b) methods for determining the worker intake; (c) frequency of analysis; (d) minimum detection levels; and (e) action levels and actions to be taken based on the results.

10. Summing Internal and External Exposure

The staff will review the applicant's program for summing internal and external exposure in order to demonstrate compliance with the dose limits, including the procedure used for assessing worker's exposures in accordance with NRC regulatory requirements.

11. Respiratory Protection

The staff will review the applicant's respiratory protection program, including the equipment to be used, the conditions under which respiratory protection will be required for routine and nonroutine operations, the protection factors that will be applied when respirators are being used, and the locations of respiratory equipment within the plant.

12. Instrumentation

The staff will review the applicant's requirements for radiological measurement instrumentation, including the policy for the maintenance and use of operating instrumentation and the types of instruments that are available, including their ranges, counting mode, sensitivity, alarm setpoints, planned use, and frequency of calibration.

13. Integrated Safety Analysis (ISA)

In addition to the radiation protection program elements discussed above, the primary reviewer will review a sample of the postulated, higher-risk accidents in the ISA summary and other ISA documentation as needed which have radiation safety consequences for the workers (See Section 3.0, "Integrated Safety Analysis."). At a minimum, the review of the ISA summary and other ISA documentation as needed will include a review of a sample of the higher risk accident sequences that result in worker radiation exposures of concern before any controls are applied. The methodology in assessing the accident consequences, likelihood, and risk index associated with each of these accident sequences will be reviewed. Items relied on for safety established by the applicant to prevent or mitigate each accident sequence, and the levels of assurance applied to the items relied on for safety will be reviewed.

4.4 ACCEPTANCE CRITERIA

The applicant's radiation protection program is acceptable if the applicant provides data and information that meet the acceptance criteria for each element in this section.

4.4.1 ALARA (As Low As Is Reasonably Achievable)

4.4.1.1 Regulatory Requirements

Regulations applicable to the ALARA program are the following from Title 10, CFR:

1.	Section 19.12	"Instructions to workers"
2.	Section 20.1101	"Radiation protection programs"
3.	Section 20.2102	"Records of radiation protection programs"
4.	Section 20.2110	"Form of records"
5.	Section 20.2105	"Records of Planned Special Exposures"

4.4.1.2 Regulatory Guidance

NRC regulatory guides applicable to the ALARA program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.1.1 are:

1.	Regulatory Guide 8.2 February 2, 1973	*Guide for Administrative Practice in Radiation Monitoring*
2.	Regulatory Guide 8.10, Rev. 1-R, May 1977	*Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable*
3.	Regulatory Guide 8.13, Rev. 3	*Instructions Concerning Prenatal Radiation*

	Draft DG 8014, October 1994	Exposure
4.	Regulatory Guide 8.29 February 1996	*Instructions Concerning Risks from Occupational Radiation Exposure*

4.4.1.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's ALARA program is acceptable if it fulfills the following criteria: (1) the applicant commits to a comprehensive, effective, and written ALARA program; (2) the ALARA committee is evidenced by an organizational structure in which radiation protection personnel interact, in a timely manner, with production personnel to ensure that methods and techniques for reducing occupational radiation exposure are incorporated in facility operation and design; (3) the ALARA committee, or other similar safety committee, is responsible for conducting periodic reviews of the radiation protection program at least annually and documenting their results. The committee's membership includes management representatives of radiation protection, environmental, safety, and production; (4) the ALARA committee considers the ISA in determining whether further reduction in occupational radiation exposures are reasonable; and (5) the recommendations of the ALARA committee are documented and tracked to completion.

The committee's review includes evaluation of the results of audits made by the radiation protection organization, reports of radiation levels, contamination levels, employee exposures, waste management, and effluent releases. The review determines:

1. If there are any upward trends in personnel exposure for identified categories of workers or types of operations, or effluent releases.
2. If exposures and releases are being lowered or maintained in accordance with the ALARA concept.

3. If equipment for effluent and exposure controls is being properly used, maintained, and inspected.

Trend analysis is performed in the following areas:

1. Radiation exposures of plant workers and members of the public.

2. Concentrations of airborne radioactivity in plant areas.

3. Concentrations of radioactive material in gaseous and liquid effluents.

4. Radioactive contamination in plant areas and on equipment.

5. Operation of radiation measurement instrumentation.

6. Operation of respiratory protection equipment.

7. Operation of effluent filtration systems.

4.4.2 Organizational Relationships and Personnel Qualifications

4.4.2.1 Regulatory Requirements

Regulations applicable to organizational relationships and personnel qualifications of the radiological protection staff are the following from Title 10CFR:

1. Section 70.22 "Contents of applications."

2. Section 70.23 “Requirements for the approval of applications”

4.4.2.2 Regulatory Guidance

NRC regulatory guides applicable to organizational relationships and personnel qualifications that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.2.1 are:

1.	Regulatory Guide 8.2 February 1973	*"Guide for Administrative Practice in Radiation Monitoring"*
2.	Regulatory Guide 8.10, Rev. 1-R, May 1977	*"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"*

4.4.2.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant’s radiation safety program organizational relationships and personnel qualifications are acceptable if they fulfill the following criteria: (1) the applicant identifies and includes the authority and responsibility of each position identified; (2) the applicant describes the organizational relationships that are to exist between the individual positions responsible for the radiation safety program and other line managers; (3) the Plant Manager, or equivalent, has overall responsibility and authority for safety; (4) the Radiation Safety Manager, or equivalent, has direct responsibility for establishing and implementing the radiation protection program and has direct access to the Plant Manager; and (5) Radiation Safety Specialist(s) are responsible for specific activities assigned to the radiation safety program with radiation safety technicians implementing these functions. Certain radiation safety technical support and/or audit activities may be supplied by qualified off-site corporate or consultant organizations.

Radiation Protection personnel meet the following education and experience criteria:

1. The Radiation Safety Manager has a bachelor’s degree in Science or Engineering, at least 5 years experience as a Health Physicist, and at least 1 year of experience as a Health Physicist in a uranium fuel fabrication facility.

2. Radiation safety specialist has a bachelor's degree in Science or Engineering and at least 1 year of applied health physics experience at a nuclear facility.

3. Radiation safety technicians have a high school diploma or equivalent and certification in a technician trainee program.

4.4.3 Radiation Safety Procedures and Radiation Work Permits (RWPs)

4.4.3.1 Regulatory Requirements

The regulations applicable to approved operating procedures and RWPs are the following from Title 10, CFR:

1. Section 70.22 "Contents of applications"

2. Section 70.23 "Requirements for the approval of applications"

4.4.3.2 Regulatory Guidance

Regulatory guidance applicable to procedures and RWPs that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.3.1. is Regulatory Guide 8.10, Rev., 1-R, May 1977, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable."

4.4.3.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's radiation safety procedures and RWPs are acceptable if they fulfill the following criteria: (1) written, approved radiation safety procedures and RWPs are used to carry out activities related to the radiation safety program and the procedures and RWPs are reviewed, revised, and updated periodically; (2) a mechanism for providing a current copy of the procedures to personnel is established; (3) procedures are reviewed and approved by the Radiation Safety Manager, or an individual who has the qualifications of the Radiation Safety Manager, and at intervals no longer than every 2 years, the procedures are revised and updated as necessary; (4) the applicant makes a commitment to use special reviews and approvals before conducting an activity involving licensed materials with an RWP that is not covered by a written radiation safety procedure; (5) the applicant specifies how the determination is made to use an RWP, the positions within the organization authorized to approve and issue an RWP, the types of information that will be included in an RWP, the provisions for updating and terminating an RWP, and the records to be kept for the RWPs; (6) the applicant specifies the levels of approval necessary for an RWP before it can become effective and that the RWP is approved and signed by a supervisor or specialist in radiation protection; (7) approvals are required from other involved groups to ensure that the provisions of the RWP cover all potential hazards and that the operations are conducted according to proper standards; and (8) the applicant commits to a system that ensures that RWPs are not used past their termination dates. The system includes what types of records

are to be kept, the retention times for these records, and the final disposition of the RWP. The record system is sufficient to allow independent auditors to reconstruct the circumstances necessitating the RWP, the factors included, and the results.

The applicant commits to using RWPs for specific purposes only and RWPs are reissued when significant changes in the task or changes that affect the safety of the worker are made. The applicant states that the RWP includes a list of the safety requirements for work conducted under the authorization and includes at least the following, as applicable: (1) the type and frequency of personal monitoring to be conducted; (2) the total time allotted for the authorization; (3) special shielding or ventilation to be used; (4) personal protective equipment; (5) work limitations; (6) radiological conditions; and (7) special instructions.

4.4.4 Training

4.4.4.1 Regulatory Requirements

Regulations applicable to the radiation safety training program are the following from Title 10, CFR:

1.	Section 19.12	"Instructions to workers"
2.	Section 20.2110	"Form of records"

4.4.4.2 Regulatory Guidance

NRC regulatory guides and ANSI and American Society for Testing and Materials (ASTM) standards provide information, recommendations and guidance, and, in general, describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.4.1. are:

1.	Regulatory Guide 8.10, Rev. 1-R May 1977	*"Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable"*
2.	Regulatory Guide 8.13, *Draft DG-801 proposed* R-3 October 1994	*"Instructions Concerning Prenatal Radiation Exposure"*
3.	Regulatory Guide 8.29, *Draft DG-8012 proposed* R-1 December 1994	*"Instructions Concerning Risks from Occupational Radiation Exposure"*
4.	ASTM C986-89 Reapproved 1995	"Developing Training Programs in the Nuclear Fuel Cycle"

5.	ASTM E1168-95	"Radiological Protection Training for Nuclear Facility Workers"

4.4.4.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's training program is acceptable if it fulfills the following criteria: (1) all personnel and visitors entering restricted areas either receive training in radiation protection or are escorted by an individual who has received such training; (2) the technical content of the training program is commensurate with the potential radiological health protection problems in the restricted area and meets the requirements of 10 CFR Parts 19 and 20; (3) the training covers the following areas, as appropriate, in sufficient depth for the specific types of functions: (a) access and egress controls and escort procedures; (b) radiation safety principles, policies, and procedures; (c) monitoring for internal and external exposures; (d) personnel dosimeters; (e) monitoring instruments; (f) contamination control, including protective clothing and equipment; (g) radiation area and airborne radioactive area; (h) use, storage, and transfer of radioactive materials; (i) posting and labeling requirements; (j) ALARA and exposure limits; (k) radiation hazards and health risks; (l) practical training; and (m) emergency response requirements for individuals; (4) refresher training is completed not later than 2 years following the most recent training and consists of a condensed version of the initial training, with emphasis on changes in policies, procedures, requirements, and facilities; and (5) the effectiveness of the training program is evaluated by written tests or other methodologies and includes evaluation of the curriculum and the instructor's qualifications.

4.4.5 Ventilation Systems

4.4.5.1 Regulatory Requirements

Regulations applicable for the ventilation system are the following from Title 10, CFR:

1.	Section 20.1701	*Use of process or other engineering controls*
2.	Section 20.2110	*Form of records*

4.4.5.2 Regulatory Guidance

NRC regulatory guides, ANSI standards, and National Council on Radiation Protection and Measurements (NCRP) report applicable to the regulatory requirements related to the ventilation system that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.5.1. are:

1.	Regulatory Guide 8.24, Rev. 1 October 1979	*"Health Physics Surveys during Enriched Uranium-235 Processing and Fuel Fabrication"*
2.	ANSI N510-1980	"Testing of Nuclear Air Cleaning Systems"

3.	ERDA 76-21	"Nuclear Air Cleaning Handbook," C. A. Burchsted, A. B. Fuller, J. E. Kahn
4.	NCRP Report No. 59 December 15, 1978	"Operational Radiation Safety Program"

4.4.5.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's ventilation systems are acceptable if they fulfill the following criteria: (1) the applicant commits to a policy for designing and operating the ventilation systems in the facility in a manner that protects workers and the public from airborne radioactive material and assures that the limits of 10 CFR Part 20 are not exceeded during normal operations; (2) the applicant specifies criteria for the ventilation systems, including minimum flow velocity at openings of hoods, maximum differential pressure across filters, and types of filters to be used, where applicable; (3) the applicant specifies the frequency and types of tests required to measure ventilation system performance, the acceptance criteria, and the actions to be taken when the acceptance criteria are not satisfied; (4) the applicant describes the maintenance, QA, fire safety, criticality safety, and chemical process safety activities associated with the ventilation systems' structures, systems, and components that are identified in the ISA summary as items relied on for safety; (5) airflow patterns are from areas of lesser contamination potential to areas of greater contamination potential; and (6) engineering controls are used to limit the intake of radioactive material, including portable filtration systems used to control airborne contaminants and containment structures to protect personnel working in adjacent areas, when feasible.

4.4.6 Air Sampling

4.4.6.1 Regulatory Requirements

NRC regulations applicable to the air sampling/monitoring program are the following from Title 10, CFR:

1.	Section 20.1204	*Determination of internal exposure*
2.	Section 20.1703	*Use of individual respiratory protection equipment*
3.	Section 20.1902	*Posting requirements of airborne radioactive areas*
4.	Section 20.2103	*Records of surveys*
5.	Section 20.2110	*Form of records*
6.	Section 20.2203(a)(3)(i) and (ii), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*

4.4.6.2 Regulatory Guidance

NRC regulatory guides, and NUREGs, and ANSI standards applicable to the air sampling/monitoring program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.6.1. are:

1.	Regulatory Guide 8.2 February 1973	*"Guide for Administrative Practice in Radiation Monitoring"*
2.	Regulatory Guide 8.24, Rev. 1 October 1979	"Health Physics Surveys During Enriched *Uranium-235 Processing and Fuel Fabrication"*
3.	Regulatory Guide 8.25, Rev. 1 June 1992	*"Air Sampling in the Workplace"*
4.	NUREG-1400 September 1993	*"Air Sampling in the Workplace"*
5.	ANSI N13.1-1969 Reaffirmed 1993	*"Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities"*

4.4.6.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's air sampling program is acceptable if it fulfills the following criteria: (1) the applicant commits to provide representative air sampling for all areas in which a potential exists for airborne radioactive materials; (2) the air sampling data is provided that demonstrates exposures do not exceed established limits and that exposures are maintained ALARA; (3) the applicant provides for each work area a determination that the frequency for analyzing the airborne level of radioactivity, the counting techniques, and the method for determining the airborne concentration are adequate; (3) the calibration methods and frequencies that ensure proper operation of the instrumentation, including the operation of flow rate meters, and the calculations of airborne concentrations, in various areas, to obtain the airborne levels, are described; (4) the application contains a description of action levels, alarm setpoints, frequency of measurements, and action to be taken when action levels are exceeded; (5) the application includes a description of where CAMs are used, the readouts, annunciators, and alarms; and (6) the applicant demonstrates that the action levels used are based on appropriate technical criteria to determine the necessary controls. The demonstration includes the minimum detectable activities (MDAs) for the specific radionuclides of interest.

4.4.7 Contamination Control

4.4.7.1 Regulatory Requirements

NRC regulations applicable to the contamination control program are the following from Title 10, CFR:

1.	Section 20.1501(a)(2)(ii) and (iii)	“Surveys and Monitoring - General”
2.	Section 20.1703(a)(3)(ii)	"Use of individual respiratory protection equipment"
3.	Section 20.1901	"Caution signs"
4.	Section 20.1902(e)	"Posting requirements"
5.	Section 20.1904	"Labeling containers"
6.	Section 20.1906	"Procedures for receiving and opening packages"
7.	Section 20.2103	"Records of surveys"
8.	Section 20.2110	"Form of records"
9.	Section 20.2203(a)(3)(i) and (ii), and (b)	"Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits"

4.4.7.2 Regulatory Guidance

NRC regulatory guides, NRC Branch Technical Positions, and ANSI standards applicable to the contamination control program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.7.1 are:

1.	Regulatory Guide 8.1 February 1973	*Radiation Symbol*
2.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
3.	Regulatory Guide 8.24, Rev. 1 October 1979	*Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication*
4.	ANSI N328-1978	*Radiation Protection Instrumentation Test and Calibration*
5.	ANSI N512-1974, Appendix A	*Protective Coatings (Paints) for the Nuclear Industry*, *Leak Test Methods*
6.	ANSI N542-1977	*Sealed Radioactive Sources Classification*

7. NRC Branch Technical Position *License Condition for Leak Testing Sealed Byproduct Material Sources, April 1993*

8. NRC Branch Technical Position *License Condition for Leak Testing Sealed Plutonium Sources, April 1993*

9. NRC Branch Technical Position *License Condition for Plutonium Alpha Sources, April 1993*

10. NRC Branch Technical Position *License Condition for Leak Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters, April 1993*

11. NRC Branch Technical Position *License Condition for Leak Testing Sealed Uranium Sources, April 1993*

12. NRC Branch Technical Position *Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material, April 1993*

4.4.7.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's contamination control program is acceptable if it fulfills the following criteria: (1) the applicant commits to establishing a contamination survey program, based on the specifications in Regulatory Guide 8.24, that includes the types and frequencies of surveys, limits for contamination levels, and methods and instruments used in the surveys; (2) contamination surveys are conducted routinely for the areas of the plant site where contamination is likely, and the methods and types of instruments used in the surveys are adequate to allow accurate assessment of working conditions; (3) information is provided about survey frequency for each area, the types of radiation, the criteria for contamination levels for both removable and fixed contamination and the action levels and actions (including the time frame for action initiation and completion) to be taken when the levels are exceeded; (4) instruments with sufficient sensitivity to measure contamination at or below the action level are available for use; (5) the features of the facility that help control contamination including step-off pads, personal monitoring equipment at exits, and change rooms are described; (6) the following are specified: (a) the types and availability of contamination monitoring equipment, (b) the specific limits established for personnel contamination, (c) the minimum provisions for personnel decontamination, (d) the minimum types of protective clothing necessary for individuals to enter restricted areas, and (e) the technical criteria and levels for defining contamination areas; and (7) the policy on the use of personnel monitoring equipment is stated and personnel perform a whole body survey each time they leave known contaminated areas, or a minimum of a hand and shoe survey each time they leave restricted areas that are potentially contaminated.

The applicant's sealed sources are leak tested on a regular basis in accordance with NRC's Branch Technical Positions: (1) "License Condition for Leak Testing Sealed Byproduct Material Sources," April 1993; (2) "License Condition for Leak Testing Sealed Plutonium Sources," April 1993; (3) "License Condition for Plutonium Alpha Sources," April 1993; (4) "License Condition for Leak Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993; and (5) "License Condition for Leak Testing Sealed Uranium Sources," April 1993. The applicant has written procedures for leak testing sealed sources in accordance with NRC's Branch Technical Positions described above. The procedures include at least the acceptable contamination levels, test frequencies, and actions to be followed, if limits are exceeded.

The applicant commits to a periodic review of all aspects of access control to determine that: (1) signs, labels, and other access controls are properly posted and operative; (2) restricted areas established to prevent the spread of contamination are identified with appropriate signs; and (3) step-off pads, change facilities, protective clothing facilities, and personnel monitoring instruments are provided in sufficient numbers and locations. The reviews are documented, along with any deficiencies, and the corrective actions taken.

A system is established to ensure that equipment and materials removed from contaminated areas are not contaminated above specified release levels. The radiological contamination levels of items (e.g., tools, equipment, material, premises, or scrap) given clearance for release for unrestricted use are in accordance with NRC's Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," dated April 1993. Maximum permissible personnel contamination levels (skin and clothing) are established. Detected contamination in excess of these levels is investigated and documented as to source, probable cause, and other pertinent information. Records of these investigations are maintained and reviewed by radiation protection management for trends and corrective action taken, as necessary.

4.4.8 External Exposure

4.4.8.1 Regulatory Requirements

NRC regulations applicable to the measuring, documenting, and maintaining the external exposure of personnel are the following from Title 10, CFR:

1.	Section 19.13	*Notifications and reports to individuals*
2.	Section 20.1201(a)(1)(2) and (c)	*Occupational dose limits for adults*
3.	Section 20.1301(a)(1) and (2), (b) and (c)	*Dose limits for individual members of the public*
4.	Section 20.1302 (a), (b)(1), and (b)(2)(ii)	*Compliance with dose limits for individual members of the public*

5.	Section 20.1501(a)(2)(i) and (c)	*Surveys and Monitoring ! General*
6.	Section 20.1502(a)	*Conditions requiring individual monitoring of external and internal occupational dose*
7.	Section 20.1601	*Control of access to high radiation areas*
8.	Section 20.1901	*Caution signs*
9.	Section 20.1902(a)	*Posting requirements*
10.	Section 20.1906	*Procedures for receiving and opening packages*
11.	Section 20.2101	*Records ! General Provisions*
12.	Section 20.2103	*Records of surveys*
13.	Section 20.2106	*Records of individual monitoring results*
14	Section 20.2110	*Form of records*
15.	Section 20.2202(a), (b), (c), and (d)	*Notification of incidents*
16.	Section 20.2203(a)(2), (a)(3)(i) and (ii), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*
17.	Section 20.2206	*Reports of individual monitoring*

4.4.8.2 Regulatory Guidance

NRC regulatory guides and ANSI standards applicable to measuring, documenting, and maintaining the external exposure of personnel below the applicable external exposure limits that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.8.1. are:

1.	Regulatory Guide 8.1 February 1973	*Radiation Symbol*
2.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
3.	Regulatory Guide 8.4 February 1973	*Direct-Reading and Indirect-Reading Pocket* Dosimeters

4.	Regulatory Guide 8.7, *Rev. 1 June 1992*	*Instructions for Recording and Reporting Occupational Radiation Exposure Data*
5.	Regulatory Guide 8.24, *Rev. 1 October 1979*	*Health Physics Survey During Enriched Uranium-235 Processing and Fuel Fabrication*
6.	Regulatory Guide 8.34 July 1992	*Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*
7.	ANSI N13.11-1983	*Dosimetry ! Personnel Dosimetry Performance ! Criteria for Testing*
8.	ANSI N13.15-1985	*Radiation Detectors ! Personnel Thermoluminescence Dosimetry Systems ! Performance*
9.	ANSI N13.27-1981	*Performance Requirements for Pocket-Sized Alarm Dosimeters and Alarm Ratemeters*
10.	ANSI N322-1977	*Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters*

4.4.8.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's external exposure program is acceptable if it fulfills the following criteria: (1) the applicant commits to a personnel monitoring program for external radiation, that provides a method to measure, assess, and record personnel exposure to radiation and commits to an ALARA philosophy; (2) the types of monitoring equipment that are used and the types of radiation that are measured are described and justified.. Regulatory Guide 8.34, *"Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"*, provides guidance for determining who is required to wear personnel monitoring dosimeters; (3) the type, range, sensitivity, accuracy, and frequency for reading personnel dosimeters and recording the radiation dose of the dosimeter reading are stated and justified; (4) the use of dosimetry results as a guide to operational planning are described and justified; (5) the specific exposure levels below the regulatory requirements at which action are taken to investigate the cause of the exposures and to reduce exposures are specified; and (6) all personnel dosimeters (except for those specified in 10 CFR 20.1501(c)) are processed and evaluated by a dosimetry processor holding accreditation from the National Voluntary Laboratory Accreditation Program of the National Institute of Standards and Technology.

4.4.9 Internal Exposure

4.4.9.1 Regulatory Requirements

NRC regulations applicable to the measuring, documenting, and maintaining the internal exposure of personnel below the applicable internal exposure limits are the following from Title 10, CFR:

1.	Section 19.13	*Notifications and reports to* individuals
2.	Section 20.1201 a(1),(d), and (e)	*Occupational dose limits for adults*
3.	Section 20.1204	*Determination of internal exposure*
4.	Section 20.1301(a)(1), (b),(c)	*Dose limits for individual members of the public*
5.	Section 20.1302(a) and (b)(1)	*Compliance with dose limits for individual members of the public*
6.	Section 20.1502(b)	*Conditions requiring individual monitoring of external and internal occupational dose*
7.	Section 20.1703(a)(3)(ii) and (b)	*Use of individual respiratory protection equipment*
8.	Section 20.1901	*Caution signs*
9.	Section 20.1902(d)	*Posting requirements*
10.	Section 20.2101	*Records ! General Provisions*
11.	Section 20.2103	*Records of surveys*
12.	Section 20.2106	*Records of individual monitoring results*
13.	Section 20.2110	*Form of records*
14.	Section 20.2202(a), (b), (c), and (d)	*Notification of incidents*
15.	Section 20.2203(a)(2), (b), and (d)	*Reports of exposures, radiation levels, and concentrations of radioactive material exceeding the limits*
16.	Section 20.2206	*Reports of individual monitoring*

4.4.9.2 Regulatory Guidance

NRC regulatory guides and ANSI standard applicable to the measuring, documenting, and maintaining the internal exposure of personnel below the applicable internal exposure limits that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.9.1. are:

1.	Regulatory Guide 8.1 February 1973	*Radiation Symbol*
2.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
3.	Regulatory Guide 8.7, *Rev. 1 June 1992*	*Instructions for Recording and Reporting Occupational Radiation Exposure Data*
4.	Regulatory Guide 8.9, *Rev. 1* July 1993	*Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program*
5.	Regulatory Guide 8.24, *Rev. 1 October 1979*	*Health Physics Surveys During Enriched Uranium-235 Processing and Fuel Fabrication*
6.	Regulatory Guide 8.25, Rev. 1 June 1992	*Air Sampling in the Workplace*
7.	Regulatory Guide 8.34 July 1992	*Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*
8.	ANSI.HPSN 13.22, 1995	*"Bioassay Program for Uranium"*
9.	ANSI.HPSN 13.30, 1996	"Performance Criteria for Radiobioassay"

4.4.9.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's program for internal exposure is acceptable if the applicant meets the requirements of 10 CFR 20.1201, 20.1204, and 20.1502(b). Regulatory Guides 8.25, *"Air Sampling in the Workplace"*; 8.34, *"Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"*; 8.9, Rev. 1, *"Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program"* and ANSI.HPSN 13.22, 1995, "Bioassay Program for Uranium" provide information, recommendations, and guidance and a basis acceptable to the staff for implementing the internal exposure program.

The applicant establishes a program for monitoring worker internal exposures. The program specifies the criteria for participation, the frequency of measurements, the methods to be used, the frequency of analysis, the minimum detection levels, and the action levels and actions to be taken on the results. In addition, the program specifies: (1) the methods for determining if monitoring of worker internal exposure is needed; (2) the criteria for determining when it is necessary to monitor an individual's internal exposure during work hours; and (3) the methods for determining the worker intake from (a) the concentrations of radioactive materials in the work area air, (b) the quantities of radionuclides in the body, (c) the quantities of radionuclides excreted from the body, or (d) any combination of the above methods as may be necessary for

determining the intake. If soluble uranium material is present in work area air, action levels based on the chemical toxicity is established.

When air sampling measurement results are used for determining worker intake, the applicant specifies the frequency of sampling and data analysis, the minimum detection levels, and the action levels and actions to be taken on the results.

When bioassay results are used for determining worker intake, the applicant specifies the types of bioassay to be used, the frequency of data collection for each type of measurement, the minimum detection levels, and the action levels and actions to be taken on the results. The applicant commits to a continuing quality assurance and control programs on all phases of its bioassay program, including such items as sample collection, qualifications of laboratory personnel, laboratory intercomparisons, computational checks, and use of appropriate blanks and standards.

4.4.10 Summing Internal and External Exposure

4.4.10.1 Regulatory Requirements

NRC regulations applicable to summing internal and external exposures are the following from Title 10, CFR:

1.	Section 20.1201(a)(1) and (f)	*Occupational dose limits for adults*
2.	Section 20.1202	*Compliance with requirements for summation of external and internal doses*
3.	Section 20.1207	*Occupational dose limits for minors*
4.	Section 20.1208	*Dose to an embryo/fetus*
5.	Section 20.2101	*Records ! General Provisions*
6.	Section 20.2103	*Records of surveys*
7.	Section 20.2104	*Determination of prior occupational dose*
8.	Section 20.2106	*Records of individual monitoring results*
9.	Section 20.2110	*Form of records*
10.	Section 20.2202(a), (b), (c), and (d)	*Notification of incidents*
11.	Section 20.2203(a)(2),	*Reports of exposures, radiation levels, and*

	(b), and (d)	*concentrations of radioactive material exceeding the limits*
12.	Section 20.2206	*Reports of individual monitoring*
13.	Section 20, Subpart D	*Radiation Dose Limits for Individual Members of the Public*

4.4.10.2 Regulatory Guidance

NRC regulatory guides, and ANSI standards applicable to the summing of internal and external exposures that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.10.1 are:

1.	Regulatory Guide 8.2 February 1973	*Guide for Administrative Practice in Radiation Monitoring*
2.	Regulatory Guide 8.7, *Rev. 1 June 1992*	*Instructions for Recording and Reporting Occupational Radiation Exposure Data*
3.	Regulatory Guide 8.34 July 1992	*Monitoring Criteria and Methods to Calculate Occupational Radiation Doses*
4.	Regulatory Guide 8.36 July 1992	*Radiation Dose to the Embryo/Fetus*
5.	ANSI N13.6-1966 Reaffirmed 1989	"*Practice for Occupational Radiation Exposure Records Systems"*

4.4.10.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's method for summing internal and external exposures is acceptable if the applicant commits to a procedure for combining internal and external exposures in accordance with Regulatory Guide 8.7, Rev. 1, *"Instructions for Recording and Reporting Occupational Radiation Exposure Data"*; 8.34, *"Monitoring Criteria and Methods to Calculate Occupational Radiation Doses"*; and 8.36, *"Radiation Dose to the Embryo/Fetus"*.

4.4.11 Respiratory Protection

4.4.11.1 Regulatory Requirements

NRC regulations applicable to respiratory protection are the following from Title 10, CFR:

1.	Section 20.1701	*Use of process or other engineering controls*

2.	Section 20.1702	*Use of other controls*
3.	Section 20.1703(a), (c), and (d)	*Use of individual respiratory protection equipment*
4.	Section 20.2110	*Form of records*

4.4.11.2 Regulatory Guidance

The NRC regulatory guide and ANSI standards applicable to the respiratory protection program that in general describe a basis acceptable to the staff for implementing the regulatory requirements Section 4.4.11.1 are:

1.	Regulatory Guide 8.15 October 1976	*Acceptable Programs for Respiratory Protection*
2.	ANSI Z88.2-1992	*Practices for Respiratory Protection*

4.4.11.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's respiratory protection program is acceptable if it fulfills the following criteria: (1) the applicant commits to establishing a respiratory program that meets the requirements of 10 CFR Part 20, Subpart H; (2) the application describes the equipment to be used, the conditions under which respiratory protection are required for routine and nonroutine operations, the protection factors that are applied when respirators are being used, and the locations of respiratory equipment within the plant. ANSI Z88.2, which defines responsibilities and requirements in the areas of (a) training, (b) control and use of respiratory equipment, (c) mask-fit testing, and (d) breathing-air purity, may be used as guidance; (3) the applicant describes: (a) the types of engineering and administrative controls that have been implemented to reduce the risk of internal exposure without the need for respiratory protection and (b) the methods for determining exposure while an individual is using respiratory protection to ensure that a proper estimate of exposure and internal dose is made. Factors that are critical in this calculation include the time of exposure to airborne radioactive materials, the protection factor for the respirator, the proper fitting of the equipment before use, and the measurement of the concentrations of radioactive material during the exposure.

4.4.12 Instrumentation

4.4.12.1 Regulatory Requirements

NRC regulations applicable to the instrumentation program are the following from Title 10, CFR:

1.	Section 20.1501(b)(c)	*Surveys and Monitoring ! General*
2.	Section 20.2103	*Records of survey*

4.4.12.2 Regulatory Guidance

NRC regulatory guides and ANSI standards applicable to the instrumentation program that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.12.1 are:

1.	Regulatory Guide 8.24, Rev. 1, October 1979	*Health Physics Surveys during Enriched Uranium-235 Processing and Fuel Fabrication*
2.	ANSI N13.4-1971	*Specification of Portable X- or Gamma-Radiation Survey Instruments*
3.	ANSI N42.12-1980	*Calibration and Usage of Sodium Iodide Detector Systems*
4.	ANSI N42.15-1980	*Performance Verification of Liquid-Scintillation Counting Systems*
5.	ANSI N42.17A-1989	*Performance Specifications for Health Physics Instrumentation ! Portable Instrumentation for Use in Normal Environmental Conditions*
6.	ANSI N42.17B-1989	*Performance Specifications for Health Physics Instrumentation ! Occupational Airborne Radioactivity Monitoring Instrumentation*
7.	ANSI N323-1978	*Radiation Protection Instrumentation Test and Calibration*

4.4.12.3 Regulatory Acceptance Criteria

The reviewer will determine that the applicant's instrumentation is acceptable if it fulfills the following criteria: (1) the applicant commits to a policy for the maintenance and use of operating instruments in sufficient number and types to meet the requirements specified in 10 CFR Part 20; (2) the applicant has adequate radiation measuring instruments for routine and emergency operations and includes a listing of the types of instruments that are available, including ranges, counting mode, sensitivity, alarm setpoints, planned use, and frequency of calibration; (3) the applicant commits to calibrate instruments at least annually, preferably semiannually, and recalibrates instruments if the equipment is repaired such that the accuracy of the reading is affected; (4) the applicant justifies the criteria for selecting radiation measurement instruments for: (a) performing radiation and contamination surveys, (b) sampling airborne radioactivity, (c) monitoring area radiation, (d) monitoring personnel, and (e) performing radioactive analyses; (5) instrument calibrations are traceable to a recognized standard such as National Institute of Standards and Technology (NIST); and (6) the applicant describes the (a) instrument storage, calibration, and maintenance facilities; and (b) the

laboratory facilities for radiological analyses. Guidance on instrumentation and instrumentation calibration is provided in ANSI N42.17A and ANSI N323.

4.4.13 Integrated Safety Analysis (ISA)

4.4.13.1 Regulatory Requirements

The regulation applicable to the ISA is 10 CFR Part 70.62.

4.4.13.2 Regulatory Guidance

The NRC NUREGs applicable to the ISA that in general describe a basis acceptable to the staff for implementing the regulatory requirements of Section 4.4.13.1 are:

1.	NUREG - 1513	Integrated Safety Analysis Guidance Document
2.	NUREG/CR-6410 April 1998	Nuclear Fuel Cycle Facility Accident Analysis Handbook

4.4.13.3 Regulatory Acceptance Criteria

The applicant considers accident sequences that could result in radiological consequences of concern as defined in 10 CFR 70.61 as part of the ISA. Radiological safety assessments that support the ISA (1) use appropriate and verified assessment methods, computer codes, and literature values, (2) consider a complete range of credible accident sequences that could adversely affect radiological exposures and cause the consequences of concern, (3) reasonably estimate radiological consequences of accident sequences, (4) identify items relied on for safety to prevent and mitigate accident sequences and radiological consequences of concern, and (5) describe and commit to appropriate management measures to ensure the availability and reliability of items relied on for safety to perform their functions when needed.

This information will likely appear in the information provided in response to SRP Section 3. The radiation safety reviewer reviews this information, regardless of where it appears in the applicant's submittal. Information provided in one section of the application need not be repeated elsewhere.

4.5 REVIEW PROCEDURES

4.5.1 Acceptance Review

The primary reviewer will review the application to determine if it contains the topics and information discussed in Section 4.3 "Areas of Review." If significant deficiencies are identified in the application, the applicant will be requested to submit additional information before the start of the safety evaluation. The primary reviewer will then determine that the applicant has

provided the information required. If necessary, a request for additional information to the applicant will be prepared in conjunction with the licensing project manager.

4.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the primary reviewer will conduct a complete review of the application and determine its acceptability in accordance with Section 4.4, “Acceptance Criteria.” For existing facilities, the reviewer will consult with the cognizant radiation protection NRC inspector to identify and resolve any issues of concern related to the licensing review. The final step for the primary reviewer will be to prepare a safety evaluation report (SER) in accordance with Section 4.6 “Evaluation Findings.” The SER will be provided to the Licensing Project Manager for the supporting licensing action.

4.6 EVALUATION FINDINGS

The reviewer will write an SER addressing each topic reviewed and explain why the NRC staff has reasonable assurance that the radiation protection part of the application is acceptable and that the health and safety of the workers is adequately protected. License conditions may be proposed to impose requirements where the application is deficient. The following kinds of statements and conclusions will be included in the staff's SER:

> The applicant has committed to an acceptable radiation safety program that includes: (1) an effective documented program to ensure that occupational radiological exposures are ALARA; (2) an organization with adequate qualification requirements for the radiation safety personnel; (3) approved written radiation safety procedures or RWPs for radiation safety activities; (4) radiation safety training for all personnel who have access to restricted areas; (5) requirements for the ventilation systems; (6) requirements for radiological air sampling; (7) requirements for control of radiological contamination within the facility; (8) programs for monitoring personnel external and internal radiation exposure; (9) a respiratory protection program; (10) requirements for radiological measurement instrumentation; and (11) appropriate radiation controls based on the ISA.
>
> The NRC staff concludes that the applicant's radiation safety program is adequate and that the applicant has the necessary technical staff to administer an effective radiation safety program that meets the requirements of 10 CFR Parts 19, 20, and 70. Conformance to the application and license conditions will ensure safe operation and will provide early detection of unfavorable trends to allow prompt corrective action.

4.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, "Domestic Licensing of Special Nuclear Material," U.S. Government Printing Office, Washington, DC.

Code of Federal Regulations, Title 10, Part 20, “Standards for Protection Against Radiation,” U. S. Government Printing Office, Washington, DC.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak Testing Sealed Plutonium Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Plutonium Alpha Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak Testing Sealed Source Which Contains Alpha and/or Beta-Gamma Emitters," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "License Condition for Leak Testing Sealed Uranium Sources," April 1993.

U.S. Nuclear Regulatory Commission, Branch Technical Position, "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of Licenses for Byproduct, Source, or Special Nuclear Material," April 1993.

5.0 NUCLEAR CRITICALITY SAFETY (NCS)

5.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant, in the license application and supported by materials on the docket, has made the appropriate commitments to develop, implement, and maintain an NCS program in support of safe operation of the facility as required generally by Federal Regulations and specifically by 10 CFR 70.24, 70.61, 70.62, 70.64, and 70.65.

5.2 RESPONSIBILITY FOR REVIEW

Primary: Nuclear Process Engineer (NCS Reviewer)

Secondary: None

Supporting: Project Manager and Fuel Cycle Inspector (As needed.)

5.3 AREAS OF REVIEW

The staff should review the application to determine whether (1) the applicant has identified and committed to the responsibilities and authorities for individuals to develop and implement the NCS program; (2) the facility management measures described in 10 CFR 70.62 have been committed to and will support implementing and maintaining the NCS program; (3) an adequate NCS program is described which includes identifying and committing to the Methodologies and Technical Practices used to ensure the safe operation of the facility as required by 10 CFR 70.24 [Criticality Accident Alarm System (CAAS)], 10 CFR 70.61 [Subcriticality of Operations and Margin of Safety for Subcriticality], 10 CFR 70.64 [Baseline Design Criteria (BDC)], and 10 CFR 70.65 [ISA Summary].

The specific areas for review are as follows:

5.3.1 Organization and Administration

The Primary Reviewer should review the application to determine whether the Organization and Administration has identified and committed to the responsibilities and authorities for individuals to develop and implement the NCS program. The following areas of the application related to the applicant's Organization and Administration should be reviewed:

4) For familiarity, the general Organization and Administration methods used by the applicant (see Section 2.0).

5) The areas of review listed in Section 2.3.1 (Organization and Administration) as they relate to NCS.
6) Experience and education requirements of NCS management positions.

5.3.2 Management Measures

The Primary Reviewer should review the application to determine whether the facility management measures in 10 CFR 70.62 have been committed to by the applicant and whether they demonstrate the applicant's ability to implement and maintain the NCS program. The following areas of the application related to the applicant's Management Measures should be reviewed:

1. Configuration Management, Procedures, Audits and Assessments, Incident Investigations, and other quality assurance elements used by the applicant (see SRP Sections 11.1 through 11.8).

2. The Training, Procedures, and Audits and Assessments programs specifically related to NCS.

5.3.3 Methodologies and Technical Practices

The Primary Reviewer should review the application to determine whether the applicant has implemented NCS Methodologies and NCS Technical Practices used to make NCS determinations to ensure the safe operation of the facility as required by 10 CFR 70.24 [CAAS], 10 CFR 70.61(d) [Subcriticality of Operations and Margin of Safety for Subcriticality], 10 CFR 70.64(a)(9) [BDC], and 10 CFR 70.65(b) [ISA Summary]. The following areas of the application related to the applicant's NCS Methodologies and NCS Technical Practices should be reviewed:

1. The commitment to use the NCS Methodologies identified by the applicant's NCS program.
2. The commitment to use the NCS Technical Practices identified by the applicant's NCS program.

3. The commitment to fulfill the requirements of 10 CFR 70.24 (CAAS) and to have a CAAS that has been incorporated into the Management Measures.

4. The commitment to detect an inadvertent nuclear criticality and promptly notify personnel which should ensure that the radiation exposure to workers shall be minimized.

5. The commitment to the requirements of 10 CFR 70.61 (Subcriticality of Operations and Margin of Subcriticality for Safety).

6. The commitment to the requirements in 10 CFR 70.64 (BDC) as they relate to NCS.

7. The areas of review listed in Section 3.3 (ISA Summary) as they relate to NCS.

5.4 ACCEPTANCE CRITERIA

To provide for NCS, the applicant's use of standards should be considered acceptable if the applicant has met the following Acceptance Criteria:

If an applicant intends to conduct activities where a standard applies and the standard has been endorsed by an NRC Regulatory Guide, then a commitment to comply with all of the requirements (i.e., “shalls”) and the appropriate recommendations (i.e., “shoulds”) of the standard should constitute an acceptable program under the NRC regulations with respect to the safety aspects addressed by the standard. Notwithstanding such a general commitment to a standard, the licensee should clarify broad requirements in the standard by more specific commitments in the application. Any variations from the requirements of the standard should be identified and justified in the application.

Individual commitments to the Acceptance Criteria are expected only when the Acceptance Criteria are relevant to the operations and materials to be licensed.

5.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65, respectively. In addition, the NCS review should be conducted to ensure compliance with 10 CFR 70.24, 70.61, and 70.62.

5.4.2 Regulatory Guidance

The NRC Regulatory Guide (RG) 3.71,*“Nuclear Criticality Safety Standards for Fuels and Materials Facilities,”* August 1998, endorses the ANSI/ANS-8 national standards listed below in part or in full.

1. ANSI/ANS-8.1-1983 (Reaffirmed in 1988), *“Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors.”*

2. ANSI/ANS-8.3-1997, *“Criticality Accident Alarm System.”*

3. ANSI/ANS-8.5-1996, *“Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material.”*

4. ANSI/ANS-8.6-1983 (Reaffirmed in 1995), *“Safety in Conducting Subcritical Neutron-Multiplication Measurements In Situ.”*

5. ANSI/ANS-8.7-1975 (Reaffirmed in 1987), *“Guide for Nuclear Criticality Safety in the Storage of Fissile Materials.”*

6. ANSI/ANS-8.9-1987 (Reaffirmed in 1995), *“Nuclear Criticality Safety Criteria for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials.”*

7. ANSI/ANS-8.10-1983 (Reaffirmed in 1988), *"Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement."*

8. ANSI/ANS-8.12-1987 (Reaffirmed in 1993), *"Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors."*

9. ANSI/ANS-8.15-1981 (Reaffirmed in 1995), *"Nuclear Criticality Control of Special Actinide Elements."*

10. ANSI/ANS-8.17-1984 (Reaffirmed in 1997), *"Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors."*

11. ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

12. ANSI/ANS-8.20-1991, *"Nuclear Criticality Safety Training."*

13. ANSI/ANS-8.21-1995, *"Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors."*

14. ANSI/ANS-8.22-1997, *"Nuclear Criticality Safety Based on Limiting and Controlling Moderators."*

15. ANSI/ANS-8.23-1997, *"Nuclear Criticality Accident Emergency Planning and Response."*

5.4.3 Regulatory Acceptance Criteria

5.4.3.1 Organization and Administration

To provide for NCS, the applicant's Organization and Administration should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application (information related to these Acceptance Criteria may be consolidated with other Organization and Administration descriptions elsewhere in the application in response to Chapter 2.0):

1. The applicant meets the Acceptance Criteria related to NCS in Section 2.4.1 (Organization and Administration).

2. The applicant commits to the requirements in ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."*

3. The applicant commits to the requirements in ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

4. The applicant commits to the intent of Section 4.11 of ANSI/ANS-8.1-1983, which is: The applicant shall commit to the use of personnel, skilled in the interpretation of data pertinent to NCS and familiar with the operation of the facility, as a resource in NCS

management decisions. These specialists should be independent of operations supervision.

5. The applicant commits to provide NCS postings for areas, operations, work stations, and storage locations that provide operators a reference for ensuring conformance and safe operation.

6. The applicant commits to the policy that: "All personnel shall report defective NCS conditions to the NCS function and take no further action not specified by approved written procedures until NCS has analyzed the situation."

5.4.3.2 Management Measures

To provide for NCS, the applicant's Management Measures required by 10 CFR 70.62 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. Training (information related to these Acceptance Criteria may be consolidated with other Training descriptions in the application in response to SRP Section 11.3):

   a. The applicant commits to the requirements in both ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety"* and ANSI/ANS-8.20-1991, *"Nuclear Criticality Safety Training."*

   b. The applicant commits to provide instruction in the Training program regarding the use of Process Variables as NCS controls.

   c. The applicant commits to provide instruction in the Training program regarding all personnel to (1) recognize the CAAS signal and (2) evacuate promptly to a safe area.

   d. The applicant commits to provide instruction in the Training program regarding the policy that: "All personnel shall report defective NCS conditions to the NCS function and take no further action not specified by approved written procedures until NCS has analyzed the situation."

2. Procedures (information related to these Acceptance Criteria may be consolidated with other Procedures descriptions elsewhere in the application in response to Section 11.4):

   a. The applicant commits to the requirements in ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

   b. The applicant commits to the policy that: "No single, inadvertent departure from a procedure could cause an inadvertent nuclear criticality."

3. Audits and Assessments (information related to these Acceptance Criteria may be consolidated with other Audit and Assessment descriptions elsewhere in the application in response to Section 11.5):

   a. The applicant commits to the requirements in ANSI/ANS-8.19-1996, *"Administrative Practices for Nuclear Criticality Safety."*

   b. The applicant commits to conducting and documenting Weekly NCS Walkthroughs (e.g., checklists) of all operating SNM process areas such that all operating SNM process areas should be reviewed at least every two weeks. Identified weaknesses should be incorporated into the facility Corrective Actions Program and should be promptly and effectively resolved. A graded approach may be used to justify an alternate plan based on the ISA.

   c. The applicant commits to conducting and documenting Quarterly NCS Audits such that all NCS aspects of Management Measures (see Sections 11.1 through 11.8) should be audited at least every 2 years. A graded approach may be used to justify an alternate plan based on the ISA.

5.4.3.3 Methodologies and Technical Practices

5.4.3.3.1 Methodologies

To provide for NCS, the applicant's commitment to NCS Methodologies should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant commits to the requirements in ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors."*

2. The applicant commits to the intent of the requirement in Regulatory Guide 3.71, *"Nuclear Criticality Safety Standards for Fuels and Materials Facilities"* related to validation reports which is: The applicant should demonstrate: (1) the adequacy of the Margin of Subcriticality for Safety by assuring that the margin is large compared to the uncertainty in the calculated value of k-eff, (2) that the calculation of k-eff is based on a set of variables whose values lie in a range for which the methodology used to determine k-eff has been validated, and (3) that trends in the bias support the extension of the methodology to areas outside the Area(s) of Applicability.

3. The applicant includes a reference to (including date and revision number) and summary description of either a manual or a documented, reviewed, and approved validation report (by NCS and Management) for each methodology which will be used to make an NCS determination (e.g., experimental data, reference books, hand calculations, deterministic computer codes, probabilistic computer codes). The summary description of the reference manual or validation report should have:

a. a summary of the theory of the methodology in sufficient detail, clarity, and lack of ambiguity that allows understanding of the methodology.

b. a commitment to apply the methodology only in the Area(s) of Applicability or provide justifications for applying the methodology outside the Area(s) of Applicability.

c. a commitment to use pertinent computer codes, assumptions, and techniques in the methodology.

d. a commitment to use proper functioning of the mathematical operations in the methodology.

e. a commitment to use the data consistently with reliable experimental measurements.

f. a commitment to use plant specific benchmark experiments and data derived therefrom that will be used to validate the methodology.

g. a commitment to determine the bias, uncertainty in the bias, uncertainty in the methodology, uncertainty in the data, uncertainty in the benchmark experiments, and Margin of Subcriticality for Safety, when using the methodology.

h. a commitment to use controlled software and hardware when using the methodology.

i. a commitment to use a verification process when using the methodology.

4. The applicant commits to have, at the facility, the reference manual or documented, reviewed, and approved validation report (by NCS and Management) for each methodology used to make an NCS determination. The manual or validation report should have:

a. a description of the theory of the methodology in sufficient detail, clarity, and lack of ambiguity that allows understanding of the methodology and independent duplication of results.

b. a description of the Area(s) of Applicability which identifies the range of values for which valid results have been obtained for the parameters used in the methodology. In accordance with the provisions in ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations With Fissionable Material Outside Reactors,"* any extrapolation beyond the Area(s) of Applicability should be supported by an established mathematical methodology.

c. a description of the use of pertinent computer codes, assumptions, and techniques in the methodology.

d. a description of the proper functioning of the mathematical operations in the methodology (e.g., mathematical testing).

e. a description of the data used in the methodology consistent with reliable experimental measurements.

f. a description of the plant specific benchmark experiments and data derived therefrom that were used for validating the methodology.

g. a description of the bias, uncertainty in the bias, uncertainty in the methodology, uncertainty in the data, uncertainty in the benchmark experiments, and Margin of Subcriticality for Safety, as well as the basis for these items, as used in the methodology. If the bias is determined to be advantageous to the applicant, the applicant shall use a bias of 0.0 (e.g., in a critical experiment where the k-eff is known to be 1.0 and the code calculates 1.02, the applicant cannot use a bias of 0.02 to allow calculations to be made above the value of 1.0).

h. a description of the software and hardware that will use the methodology.

i. a description of the verification process and results.

5. The applicant commits to incorporate each reference manual or documented, reviewed, and approved validation report (by NCS and Management) for a methodology as well as assumptions used into the facility Configuration Management program.

6. The applicant commits to performing NCS determinations using specified methods. The applicant should commit to incorporating these methods into the facility Management Measures:

a. The applicant should commit to assuming credible optimum conditions (i.e., most reactive conditions physically possible or limited by written commitments to regulatory agencies) for each Controlled Parameter unless specified controls are implemented to limit the Controlled Parameter to a certain range of values.

b. The applicant should commit to set NCS operating and safety limits derived from experimental data, reference books, hand calculations, deterministic computer codes, or probabilistic computer codes which have either a reference manual or a documented, reviewed, and approved validation report (by NCS and Management).

c. The applicant should commit to consider the variability and uncertainty in a process and the NCS subcritical limit when setting NCS safety limits.

d. The applicant should commit to consider the variability and uncertainty in a process and the NCS safety limit when setting NCS operating limits.

5.4.3.3.2 Technical Practices

To provide for NCS, the applicant's commitment to NCS Technical Practices should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. Although the applicant may use a single NCS control to maintain the values of two or more Controlled Parameters, this use constitutes only one component necessary for Double Contingency Protection.

2. Based on the Performance Requirements in 10 CFR 70.61, the applicant commits to the policy that: "No single credible event or failure could result in a criticality accident."

3. The applicant commits to the preferred use of Passive-Engineered controls to ensure NCS. The applicant should commit to the following preference, in general, for controls to ensure NCS: (1) Passive-Engineered, (2) Active-Engineered, (3) Augmented-Administrative, and (4) Simple-Administrative. When choosing not to use a Passive-Engineered control, the applicant commits to identify and provide justification in the ISA.

4. When evaluating a Controlled Parameter, heterogeneous effects are considered. Heterogeneous effects are particularly relevant for low-enriched uranium processes, where, when all other parameters are equal, heterogeneous systems are more reactive than homogeneous systems.

5. The applicant commits to incorporate Controlled Parameters into the facility Management Measures of 10 CFR 70.62.

6. The applicant commits to perform an evaluation, for all Controlled Parameters, that shows that during both normal and credible abnormal conditions, the Controlled Parameter will be maintained.

7. The applicant commits to describe Controlled Parameters used as NCS control. Examples of Controlled Parameters available for NCS control are: Mass, Geometry, Density, Enrichment, Reflection, Moderation, Concentration, Interaction, Neutron Absorber, and Volume.

8. When Controlled Parameters are controlled for safety reasons by measurement, reliable methods and instruments should be used. It is acceptable if the applicant commits to representative sampling, reliable measurement instruments and methods, and dual independent measurements where there is significant susceptibility to human error.

9. The use of Mass as a Controlled Parameter should be considered acceptable if:

   a. When a given Mass of material has been determined, a percentage factor is used to determine the Mass percentage of SNM in that material.

   b. When fixed geometric devices are used to limit the Mass of SNM, a conservative process density is used.

   c. When physical measurement of the Mass is needed, the measurement is obtained by using instrumentation.

d. When double batching of SNM is possible, the Mass of SNM is limited to no more than 45% of the minimum critical Mass based on spherical geometry.

e. When double batching of SNM is not possible, the Mass of SNM is limited to no more than 75% of the critical Mass.

10. The use of Geometry as a Controlled Parameter should be considered acceptable if:

a. Before beginning operations, all dimensions and nuclear properties which use Geometry control are verified. The facility Configuration Management program should be used to maintain these dimensions and nuclear properties.

b. When using large single units, the Margins of Safety are 90% of the minimum critical cylinder diameter, 85% of the minimum critical slab thickness, and 75% of the minimum critical sphere volume.

11. The use of Density as a Controlled Parameter should be considered acceptable if:

a. When Process Variables can affect the Density, the Process Variables are identified as items relied on for safety (IROFS) in the ISA Summary.

b. When physical measurement of the Density is needed, the measurement is obtained by using instrumentation.

12. The use of Enrichment as a Controlled Parameter should be considered acceptable if:

a. When using SNM with differing Enrichment, the SNM is segregated by Enrichment.

b. When physical measurement of the Enrichment is needed, the measurement is obtained by using instrumentation.

13. The use of Reflection as a Controlled Parameter should be considered acceptable if:

a. When investigating an individual unit, the wall thickness of the unit and all reflecting adjacent materials of the unit are considered. The adjacent materials should be farther than one foot away from the unit.

b. After identifying potential reflectors, the controls to prevent the presence of the potential reflectors are identified as IROFS in the ISA Summary.

14. The use of Moderation as a Controlled Parameter should be considered acceptable if:

a. When using Moderation, the applicant commits to the requirements in ANSI/ANS-8.22-1997, *"Nuclear Criticality Safety Based on Limiting and Controlling Moderators."*

b. When Process Variables can affect the Moderation, the Process Variables are identified as IROFS in the ISA Summary.

c. When physical measurement of the Moderation is needed, the measurement is obtained by using instrumentation.

d. When designing physical structures, the design precludes the ingress of Moderation.

e. When sampling of the Moderation is needed, the sampling program uses dual independent sampling methods.

f. When developing firefighting procedures for use in a Moderation controlled area, restrictions are placed on the use of Moderator material.

g. After evaluating all credible sources of Moderation for the potential for intrusion into a Moderation controlled area, the ingress of Moderation is precluded or controlled.

15. The use of Concentration as a Controlled Parameter should be considered acceptable if:

a. When Process Variables can affect the Concentration, the Process Variables are identified as IROFS in the ISA Summary.

b. High Concentrations of SNM in a process are precluded.

c. When using a tank containing Concentration controlled solution, the tank is normally closed.

d. When sampling of the Concentration is needed, the sampling program uses dual independent sampling methods.

e. After identifying possible precipitating agents, precautions are taken to ensure that such agents will not be inadvertently introduced.

16. The use of Interaction as a Controlled Parameter should be considered acceptable if:

a. When maintaining a physical separation between units, engineered devices (i.e., spacers) with a minimum spacing are used. The structural integrity of the spacers should be sufficient for normal and credible abnormal conditions.

17. The use of Neutron Absorber as a Controlled Parameter should be considered acceptable if:

a. When using Borosilicate-Glass Raschig Rings, the applicant commits to the requirements in ANSI/ANS-8.5-1996, *"Use of Borosilicate-Glass Raschig Rings as a Neutron Absorber in Solutions of Fissile Material."*

b. When using Fixed Neutron Absorbers, the applicant commits to the requirements in ANSI/ANS-8.21-1995, *"Use of Fixed Neutron Absorbers in Nuclear Facilities Outside Reactors."*

c. When evaluating absorber effectiveness, neutron spectra are considered (e.g., cadmium is an effective absorber for thermal neutrons, but ineffective for fast neutrons).

18. The use of Volume as a Controlled Parameter should be considered acceptable if:

a. When using Volume control, geometrical devices are used to restrict the Volume of SNM and engineered devices should limit the accumulation of SNM.

b. When physical measurement of the Volume is needed, the measurement is obtained by using instrumentation.

5.4.3.3.3 Requirements of 10 CFR 70.24 (CAAS)

To provide for NCS, the applicant's commitment to the CAAS requirements in 10 CFR 70.24 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant has documented that the facility CAAS meets the requirements of 10 CFR 70.24.

2. The applicant commits to the requirements in ANSI/ANS-8.3-1997, *"Criticality Accident Alarm System."*

3. The applicant commits to the requirements in Regulatory Guide 3.71, *"Nuclear Criticality Safety Standards for Fuels and Materials Facilities"* which effect the ANSI/ANS-8.3 standard:

a. At or above the 10 CFR 70.24 mass limits, CAAS coverage shall be required in each area in which SNM is handled, stored, or used.

b. 10 CFR 70.24 requires that each area that needs CAAS coverage to be covered by two detectors.

c. 10 CFR 70.24 requires that a CAAS be capable of detecting a nuclear criticality that produces an absorbed dose in soft tissue of 20 rads of combined neutron and gamma radiation at an unshielded distance of 2 meters from the reacting material within 1 minute.

4. The applicant commits to having a CAAS that is uniform throughout the facility for the type of radiation detected, the mode of detection, the alarm signal, and the system dependability.

5. The applicant commits to having a CAAS that is designed to remain operational during credible events such as a seismic shock equivalent to the site-specific design-basis earthquake or the equivalent value specified by the Uniform Building Code.

6. The applicant commits to having a CAAS that is designed to remain operational during credible events such as a fire, an explosion, a corrosive atmosphere, and other credible conditions.

7. The applicant commits to having a CAAS alarm that is clearly audible areas that must be evacuated or provides alternate notification methods that are documented to be effective in notifying personnel that evacuation is necessary.

8. The applicant commits to rendering operations safe, by shutdown and quarantine if necessary, in any area where CAAS coverage has been lost and not restored within a specified number of hours. The number of hours should be determined on a process by process basis because shutting down certain processes, even to make them safe, may carry a larger risk, than being without a CAAS for a short time. The applicant should commit to compensatory measures (e.g., limit access, halt SNM movement) when the CAAS system is not functioning due to Maintenance.

9. Emergency Management (information related to these Acceptance Criteria may be consolidated with other emergency management descriptions elsewhere in the application in response to Chapter 8.0):

   a. The applicant commits to the requirements in ANSI/ANS-8.23-1997, *"Nuclear Criticality Accident Emergency Planning and Response."*

   b. The applicant either has an Emergency Plan or satisfies the alternate requirements found in 70.22.(h)(1)(i).

   c. The applicant commits to provide fixed and personnel accident dosimeters in areas that require a CAAS, as well as a method for prompt onsite dosimeter readouts. These dosimeters should be readily available to personnel responding to an emergency.

   d. The applicant commits to provide emergency power for the CAAS.

5.4.3.3.4 Requirements of 10 CFR 70.61 (Subcriticality of Operations and Margin of Subcriticality for Safety)

To provide for NCS, the applicant's commitment to the Subcriticality of Operations and Margin of Safety for Subcriticality requirements in 10 CFR 70.61 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant commits to the use of NCS controls and Controlled Parameters to ensure both Subcriticality of Operations and Margin of Subcriticality for Safety. As required by ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors,"* process specifications shall incorporate margins to protect against uncertainties in process variables and against a limit being accidentally exceeded."

2. The applicant commits to the requirements in ANSI/ANS-8.7-1975, *"Guide for Nuclear Criticality Safety in the Storage of Fissile Materials."*

3. The applicant commits to the requirements in ANSI/ANS-8.9-1987, *"Nuclear Criticality Safety Criteria for Steel-Pipe Intersections Containing Aqueous Solutions of Fissile Materials."*

4. The applicant commits to the requirements in ANSI/ANS-8.10-1983, *"Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement."*

5. The applicant commits to the requirements in ANSI/ANS-8.12-1987, *"Nuclear Criticality Control and Safety of Plutonium-Uranium Fuel Mixtures Outside Reactors."*

6. The applicant commits to the requirements in ANSI/ANS-8.15-1981, *"Nuclear Criticality Control of Special Actinide Elements."*

7. The applicant commits to the requirements in ANSI/ANS-8.17-1984, *"Criticality Safety Criteria for the Handling, Storage, and Transportation of LWR Fuel Outside Reactors."*

8. If the applicant intends to use administrative k-eff margins for normal and credible abnormal conditions, the applicant commits to NRC pre-approval of the administrative margins.

9. The applicant commits to the use of controls or control barriers on IROFS to ensure that an inadvertent nuclear criticality will not occur.

10. The applicant commits to incorporating controls and control barriers into the facility Management Measures of 10 CFR 70.62.

11. The applicant commits to determining subcritical limits for k-eff calculations such that : k-subcritical = 1.0 - bias-margin, where margin includes adequate allowance for uncertainty in the methodology, data, and bias to assure subcriticality.

12. The applicant commits to performing studies to correlate the change in a value of a Controlled Parameter and its k-eff value. The studies should also include changing the value of one Controlled Parameter and determining its effect on another Controlled Parameter and k-eff.

13. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) as they relate to Subcriticality of Operations and Margin of Subcriticality for Safety.

Note: This is the Acceptance Criteria to review the High-Risk Accident Sequences and a cross-section of Low-Risk Accident Sequences.

5.4.3.3.5 Requirements of 10 CFR 70.64 (BDC) [for new facilities and processes only]

To provide for NCS, the applicant's commitment to the BDC requirements in 10 CFR 70.64 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. The applicant commits to the Double Contingency Principle in determining NCS controls in the design of new facilities or new processes at existing facilities.

5.4.3.3.6 Requirements of 10 CFR 70.65 (ISA Summary)

The applicant is required to meet the performance criteria in 10 CFR 70.61(b) and (c) as well as the performance requirements in 70.61(d), which include the requirement to limit the risk of an inadvertent nuclear criticality by assuring that all nuclear processes remain subcritical. The applicant's evaluation of NCS Accident Sequences should be performed in a manner consistent with the applicant's evaluation of non-NCS Accident Sequences used to meet 10 CFR 70.61(b) and (c); however 10 CFR 70.61(d) requires the applicant to use prevention methods as the primary means to meet the performance requirements of 10 CFR 70.61(b) and (c).

To provide for NCS, the applicant's commitment to the ISA requirements in 10 CFR 70.65 should be considered acceptable if the applicant has met the following Acceptance Criteria or has identified and justified an alternative in the application:

1. Accident Sequences:

   a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Accident Sequences for NCS.

   b. The applicant commits to use Appendix A of ANSI/ANS-8.1-1983, *"Nuclear Criticality Safety in Operations with Fissionable Materials Outside Reactors"* in determining Accident Sequences.

2. Consequences:

   a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Consequences for NCS.

   b. The applicant commits to the requirements in ANSI/ANS-8.10-1983, *"Criteria for Nuclear Criticality Safety Controls in Operations With Shielding and Confinement."* In addition, the applicant should commit to the requirements in RG 3.71, *"Nuclear Criticality Safety Standards for Fuels and Materials Facilities"* which effect the ANSI/ANS 8.10 standard.

3. Likelihoods:

   a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Likelihoods for NCS.

b. The applicant commits to implement an NCS program that ensures Double Contingency Protection when practicable. When evaluating Double Contingency Protection, the term “unlikely” should be used in a manner consistent with ANSI/ANS-8.1-1983.

1. Adherence to Double Contingency Protection: Each process which could have an inadvertent nuclear criticality should have Double Contingency Protection. Double Contingency Protection may be provided by either (a) At Least Two Parameter Control: the control of at least two independent process parameters or (b) Single Parameter Control: a system of multiple independent controls on a single process parameter. The At Least Two Parameter Control method is the preferred approach due to the difficulty of preventing common-mode failure when controlling only one parameter.

2. As used in Double Contingency Protection, the term “concurrent” means that the effect of the first process change persists until a second change occurs, at which point the process could have an inadvertent nuclear criticality. It does not mean that the two events initiating the change must occur simultaneously. The possibility of an inadvertent nuclear criticality can be markedly reduced if failures of NCS controls are rapidly detected and the processes rendered safe. If not, processes can remain vulnerable to a second failure for extended periods of time.

3. If the applicant adheres to Double Contingency Protection for an NCS Accident Sequence, then the Likelihood requirements of 10 CFR 70.61(b) should be considered satisfied for that Accident Sequence.

4. Exceptions to Double Contingency Protection: There may be processes where Double Contingency Protection is not practicable. In those processes, the facility should implement sufficient Redundancy and Diversity in Controlled Parameters such that at least two unlikely and concurrent events, errors, accidents, or equipment malfunctions, are necessary before an inadvertent nuclear criticality is possible. The applicant should commit in the license application to identify and provide justification in the ISA for exceptions to Double Contingency Protection.

4. Risk:

a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to Risks for NCS.

5. IROFS:

a. The applicant meets the Acceptance Criteria in Section 3.4.1 (ISA Summary) related to IROFS for NCS.

5.5 REVIEW PROCEDURES

The reviewer should use the Regulatory Guidance of this chapter; references in this chapter; the applicant's 91-01, 70.50, and 70.74 reports; and 10 CFR Part 70 Appendix A reporting requirements.

5.5.1 Acceptance Review

The Primary Reviewer should review the applicant's NCS information for completeness with respect to the requirements in 10 CFR 70.22, 70.24, 70.61, 70.62, 70.65 and the Acceptance Criteria in Section 5.4. Using guidance in the "FCLB Materials Licensing Procedures Manual," if deficiencies are identified, then either the applicant should be requested to submit additional material prior to the start of the safety evaluation or the application should be denied.

5.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the primary reviewer will conduct a complete review of the application and determine its acceptability, consulting with the supporting reviewers to identify and resolve any issues of concern related to the licensing review. The primary reviewer (acting as a secondary or supporting reviewer) should also coordinate with other reviewers concerning NCS regarding the following:

1. In support of the primary reviewer for Section 2.0, the NCS reviewer should determine whether the Acceptance Criteria in Section 2.0 have been met as they relate to NCS.

2. In support of the primary reviewer for Sections 11.1 through 11.8, the NCS reviewer should determine whether the Acceptance Criteria in Sections 11.1 through 11.8 have been met as they relate to NCS.

3. In support of the primary reviewer for Section 3.0, the NCS reviewer should determine whether the Acceptance Criteria in Chapter 3.0 have been met as they relate to NCS.

4. In support of the primary reviewer for Section 8.0, the NCS reviewer should determine whether the Acceptance Criteria in Section 8.0 have been met as they relate to NCS.

The primary reviewer should determine whether the Acceptance Criteria in Section 5.4 have been met and should prepare the SER NCS chapter in accordance with Section 5.6.

5.6 EVALUATION FINDINGS

If the staff's review verifies that sufficient information has been provided in the safety program description to satisfy the Acceptance Criteria in Section 5.4, the staff should document its review as follows:

The staff has reviewed the Nuclear Criticality Safety (NCS) program for *[name of facility*] according to Chapter 5.0 of the Standard Review Plan. The staff has reasonable assurance that:

1. The applicant will have in place a staff of managers, supervisors, engineers, process operators, and other support personnel who are qualified to develop, implement, and maintain the NCS program in accordance with the facility Organization, Administration, and Management Measures.

2. The applicant's conduct of operations will be based on NCS Methodologies and NCS Technical Practices which will ensure that the fissile material will be possessed, stored, and used safely according to the requirements in 10 CFR Part 70.

3. The applicant will develop, implement, and maintain a Criticality Accident Alarm System in accordance with the requirements in 10 CFR 70.24 and in accordance with its Emergency Management Program.

4. The applicant will have in place an NCS program in accordance with the Subcriticality of Operations and Margin of Subcriticality for Safety requirements in 10 CFR 70.61 and Baseline Design Criteria requirements in 10 CFR 70.64.

5. Based on this review, the staff concludes that the applicant's NCS program meets the requirements of 10 CFR Part 70 and provides reasonable assurance for the protection of public health and safety, including workers and the environment.

Note: The Evaluation Finding for the ISA Summary requirements for 10 CFR 70.65 should be in SRP Section 3.6.

5.7 REFERENCES

Code of Federal Regulations, Title 10, "Energy," Part 70, `Domestic Licensing of Special Nuclear Material,' U.S. Government Printing Office, Washington, DC.

LA-10860-MS, *Critical Dimensions of Systems Containing ^{235}U, ^{239}Pu, and ^{233}U*, H. C. Paxton and N. L. Pruvost, Los Alamos National Laboratory, Los Alamos, NM, 1987.

LA-12808/UC-714, *Nuclear Criticality Safety Guide*, N. L. Pruvost and H. C. Paxton, Los Alamos National Laboratory, Los Alamos, NM, 1996.

DP-1014, *Maximum Safe Limits for Slightly Enriched Uranium and Uranium Oxide*, H. K. Clark, Du Pont de Nemours and Co., Aiken, SC, 1966.

DOE/NCT-04, A Review of Criticality Accidents, W. R. Stratton, Revised by D. R. Smith, U.S. Dept. of Energy, March 1989.

Nuclear Criticality Safety -- Theory and Practice, R. A. Knief, American Nuclear Society, La Grange Park, IL, 1985.

DOE Order 420.1 (Change 2), *Facility Safety*, October 24, 1996.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

6.0 CHEMICAL PROCESS SAFETY

6.1 PURPOSE OF REVIEW

The primary purpose of the review is to determine with reasonable assurance that the applicant's facility, process design, and commitments to implement and maintain a chemical safety function will adequately protect the health and safety of workers and the public from chemical risks produced by licensed material, hazardous chemicals produced from licensed material, and from plant conditions that affect the safety of radioactive materials and thus present an increased radiation risk; during normal operations, anticipated (off-normal) events, and during accidents. This chapter facilitates the review of the chemical safety aspects for normal operations and for accidents that are analyzed in the integrated safety analysis (ISA), through interfaces with SRP Sections 3.0 and 11.0.

An additional purpose of the review is to verify with reasonable assurance that the areas of NRC responsibility, as specified in the NRC-OSHA Memorandum of Understanding (MOU) dated October 31, 1988, in the area of chemical process safety, are properly implemented by the applicant.

6.2 RESPONSIBILITY FOR REVIEW

Primary: Chemical Process Safety Reviewer (all sections of this chapter)

Secondary: None

Supporting: Project Manager and Fuel Facility Inspection Staff (as needed)
Health Physicist (for Part 20 uranium toxicity issues)

6.3 AREAS OF REVIEW

The regulation, 10 CFR 70.62, requires that a safety program be established and maintained that will provide adequate protection from licensed materials, for worker and public health and safety and the environment. A separate chemical process safety program is not required to provide chemical process safety. Applicants are required to conduct an ISA, identify accident sequences along with items relied on for safety, identify management measures that ensure items are available and reliable, maintain records that demonstrate chemical process safety compliance to the regulation and provide reporting commitments for chemical process releases if applicable.

The staff's chemical safety review should focus on the chemical safety-related accident sequences described in the ISA Summary (some of the relevant information may appear in SRP Section 3.0) and the interfaces with management measures (some of the relevant

information may appear in SRP Section 11.0) to confirm that the applicant's equipment, facilities and procedures are adequate to protect against releases and chemical exposures of licensed material, hazardous chemicals produced from licensed material and chemical risks produced from plant conditions that affect the safety of radioactive materials. Also to be reviewed is the applicant's evidence that items identified as relied on for safety would adequately mitigate or prevent such accident sequences. The review will verify that the grading of both the controls and assurances applied to such controls are appropriate for the accident risk that the controls are designed to reduce.

An additional area of review is the applicant's application of the principles of the MOU, in identifying the hazards to be evaluated in the ISA and controlled by items and management measures. The MOU delineates the areas of federal agency responsibility for chemical process safety at NRC licensed nuclear facilities. NRC is responsible for regulating: (a) radiation risk produced by radioactive materials; (b) chemical risk produced by radioactive materials; and (c) plant conditions which affect the safety of radioactive materials and thus present an increased radiation risk. Occupational risks both from plant conditions that do not affect the safety of licensed materials and from substances prior to process addition to licensed material or after process separation from licensed material are not subject to NRC regulatory oversight; therefore, these risks are not required by Part 70 to be addressed in the ISA, ISA summary, or management measures (although addressing these risks is not required, the applicant could *choose* to include them in the ISA if, for example, the ISA is also used to comply with OSHA regulatory requirements).

Specific areas to be reviewed by the staff, for commitments to protect workers and the public, and address chemical process accident sequences in the application or ISA summary, include:

6. The narrative description of the site, facility, and processes with respect to chemical safety for normal operations. This applies to substances addressed in the *NRC-OSHA* MOU.

7. The description of the unmitigated accident sequences and the applicant's quantitative interpretation of the qualitative chemical risk levels.

8. The identification and description of the adequacy of items relied on for (chemical) safety.

9. The management measures to assure the reliability and availability of items relied on for (chemical) safety.

10. The grading of safety controls and assurances placed on such controls.

11. The interface between chemical process safety and management measures and emergency management.

12. Records for chemical process safety compliance and reporting commitments for chemical releases.

13. Use of chemical baseline design criteria for new facilities or new processes (as applicable).

6.4 ACCEPTANCE CRITERIA

An applicant who has met the following acceptance criteria, should be considered to have an acceptable chemical process safety function.

6.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65. In addition, the chemical process safety review should be conducted to provide reasonable assurance of compliance with 10 CFR 70.61, 70.62, as well as 10 CFR 70.64, for new facilities or new processes.

6.4.2 Regulatory Guidance

Relevant regulatory guidance for chemical process safety includes:

1. NUREG/CR-6410, *"Nuclear Fuel Cycle Facility Accident Analysis Handbook"*, 1998.

2. NUREG-1513, *"Integrated Safety Analysis Guidance Document"*, latest revision.

3. NUREG-1601, *"Chemical Process Safety at Fuel Cycle Facilities",* 1997.

6.4.3 Regulatory Acceptance Criteria

Applicant's license application may address these criterion by reference to information supplied to satisfy SRP Section 3.0 (ISA) or other chapters of this SRP (information need not be repeated). The chemical safety reviewer reviews the application, ISA summary, and other ISA documentation as needed with respect to these acceptance criteria regardless of where the information appears. NRC should find the applicant's chemical process safety approach or function acceptable if license commitments provide chemical process safety for the workers, the public and the environment, and satisfy the following criteria:

6.4.3.1 Process Chemical Risk and Accident Sequences

The applicant provides an adequate process description that provides sufficient detail to allow an independent assessment of the chemical hazards and potential chemical accident sequences. This information should be included in the ISA summary. Additional criteria that should be addressed in an acceptable ISA summary are:

a. Process descriptions of sufficient detail are provided to support an understanding of chemical process hazards (including radiological hazards caused by or involving chemical accidents) and to allow development of potential accident sequences.

b. The applicant provides an adequate list of the consequences and likelihoods of accident sequences identified in the ISA summary involving hazardous chemicals

produced from licensed material, and chemical risks produced by plant conditions that effect the safety of radioactive materials. Each accident sequence should include the chemical hazard evaluation that identifies potential interactions of process chemicals with associated confinement vessels, process equipment, and plant personnel. The hazard evaluation should use appropriate, accepted methods.

c. The applicant identifies and uses appropriate techniques and valid assumptions in estimating the concentrations of hazardous chemicals produced from licensed material or predicting the "toxic" footprint for releases from abnormal plant condition that affects the safety of radioactive materials for comparison with the "Performance Requirements", as described in 10 CFR 70.61(b) and 70.61(c).

d. Source term and vapor dispersion models used to calculate the concentration of UF_6 and its reaction products conform to guidance on the applicability of models provided in NUREG/CR-6481, *Review of Models Used for Determining Consequences of UF_6 Release*.

e. If dispersion models are used to determine whether a release of chemicals might affect worker or public health and safety, the applicant provides evidence that the models used are appropriate to the application and that the assumed input data leads to a conservative estimate of potential consequences. Consequence analyses conform to the guidance on atmospheric and consequence modeling found in NUREG/CR-6410, *Nuclear Fuel Cycle Facility Accident Analysis Handbook*, 1998.

f. The applicant proposes appropriate chemical exposure standards to assess chemical consequences. Acceptable exposure standards include, but are not limited to, Emergency Response Planning Guidelines (ERPGs) established by the American Industrial Hygiene Association, Acute Exposure Guideline Levels (AEGLs) established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances, exposure limits established by the Occupational Safety and Health Administration or exposure limits contained in international standards organization (ISO) standards. If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the applicant may propose an alternate exposure standard accompanied by supporting documentation to justify selection of such alternative. Note: 10 CFR 70.61, "Performance Requirements" are for "acute chemical exposures", and OSHA permissible exposure limits (PELS) are typically time weighted average (TWA) values. Consequently, for ISA purposes only, acute chemical release limits may not be adjusted using the TWA calculation where concentration and time of exposure are used, unless a rational basis is provided in the ISA summary.

6.4.3.2 Items Relied on for Safety and Management Measures

The application should identify the design basis that provides safety for normal operations. A description could include specified features such as materials of construction, sizing, system fabrication, and process control schemes. Based upon a comparison of the unmitigated chemical consequences determined in 6.4.3.1 above, to the standards developed, in accordance with §70.61, the applicant should identify (in the ISA summary) chemical process safety controls (i.e., items relied on for safety) suitable to prevent or mitigate potential

accidents. Items relied on for safety also should be identified for those accident sequences containing a chemical system/process failure that ultimately lead to radiological consequences that exceed the performance requirements (basis: MOU item (c)). Management measures to assure the availability and reliability of such items relied on for safety when they are required to perform their safety functions must also be described in the application. With respect to chemical safety, acceptability of the application and ISA summary should be based upon the degree to which each satisfies the following criteria.

a. The application should describe the engineering approach, basis or schemes employed for maintaining safety in normal operations.

b. The ISA summary includes the following information: identification of the administrative and engineered controls to prevent or mitigate chemical process risks and the risk category. If applicable, the applicant should also explain how the controls and management measures have been graded commensurate with the reduction in risk that the controls are designed to achieve.

c. The application should describe the management measures proposed to assure items relied on for safety are available and reliable when required by satisfying the following criteria:

a) Engineered Controls: procedures to ensure the reliable operation of engineered controls should be briefly described (e.g., inspection and testing procedures and frequencies, calibration programs, functional tests, corrective and preventive maintenance programs, criteria for acceptable test results, etc.)

b) Administrative Controls: procedures to ensure that administrative controls will be correctly implemented when required should be briefly described (e.g., employee training an qualification in operating procedures, periodic retraining, safety work practices, development of standard operating procedures, training program evaluation, etc.)

6.4.3.3 Requirements for New Facilities or New Processes at Existing Facilities

The application should address the baseline design criteria (BDC) for new facilities or new processes at existing facilities. NUREG-1601,Section 2.4, Design Basis, contains a list if items that should be considered in an adequate facility design. With respect to chemical safety, acceptability of the application should be based upon it providing the following information:

A. A brief description of how the ISA was performed for the new process, including it's use and relationship to the performance requirements in 10 CFR 70.61, the BDC, and a defense-in-depth strategy for higher-risk accident sequences. Acceptable principles for defense-in-depth of the chemical design would be those that support hierarchy of controls with preference for prevention, mitigation, and operator intervention (in that order). For example, limiting inventory of on-site chemicals would be a preferred, preventive practice for limiting chemical safety-related accidents.

B. The descriptions of proposed facility-specific or process-specific relaxations or additions to BDC along with justification for relaxation.

C. In the ISA summary a description of how the chemical safety BDC were applied in establishing the design principles, features, and control systems of the new process.

6.5 REVIEW PROCEDURES

The reviewer should use the Regulatory Guidance stated in this chapter; references in this chapter; the applicant's 91-01, 70.50, and 70.74 reports; and 10 CFR Part 70 Appendix A reporting requirements.

6.5.1 Technical Review

The Primary Reviewer should review the applicant's chemical process safety information for completeness with respect to the requirements in 10 CFR 70.22, 70.24, 70.61, 70.62, 70.65 and the Acceptance Criteria in Section 6.4. Using guidance in the "FCLB Materials Licensing Procedures Manual," if deficiencies are identified, the applicant should either be requested to submit additional material, or the application should be denied for further safety evaluation under section 6.5.2..

6.5.2 Safety Evaluation

When an acceptable application is received from the applicant, the primary reviewer will conduct a complete review of the application and determine its acceptability, consulting with the supporting reviewers to identify and resolve any issues of concern related to the licensing review. The primary reviewer (acting as a secondary or supporting reviewer) should also coordinate with other reviewers concerning chemical safety regarding the following:

1. In support of the Primary Reviewer for Chapter 2.0, the chemical process safety reviewer should determine whether the Acceptance Criteria in Chapter 2.0 have been met as they relate to chemical process safety.

2. In support of the Primary Reviewer for Sections 11.1 through 11.8, the chemical process safety reviewer should determine whether the Acceptance Criteria in Sections 11.1 through 11.8 have been met as they relate to chemical process safety.

3. In support of the Primary Reviewer for Chapter 3.0, the chemical process safety reviewer should determine whether the Acceptance Criteria in Chapter 3.0 have been met as they relate to chemical process safety.

4. In support of the Primary Reviewer for Chapter 8.0, the chemical process safety reviewer should determine whether the Acceptance Criteria in Chapter 8.0 have been met as they relate to chemical process safety.

The Primary Reviewer should determine whether the Acceptance Criteria in Section 6.4 have been met using the review procedures in the following sections, then the reviewer should prepare the SER NCS chapter in accordance with Section 6.6

The applicant is not required to duplicate information in separate locations. For existing licensees (renewals and amendments) the chemical safety reviewer should interface with the fuel cycle facility inspection staff to obtain any insights particular to the applicant's operations that are relevant to the chemical process safety review.

6.5.2.1 Process Chemical Risks and Accident Sequences

The staff reviews the chemical risks identified in the ISA Summary against acceptance criteria in 6.4.3.1. The applicant's process safety information is reviewed and compared to the acceptance criteria in SRP Chapter 3.0, ISA. Verification of selected chemical, and physical properties and chemical incompatibilities may require the use of engineering and chemistry handbooks. NUREG-1601 may be used to determine if the safety information provided by the applicant is adequate for chemical process safety purposes.

The reviewer will make an independent judgment of the comparative risks assigned by the applicant to accident sequences identified in the ISA summary based on risk relative to other sequences (competing risks), the complexity of the sequence, plant operating history, and general industry performance. The focus will be on sequences which would exceed the performance requirements of 70.61 if they were not mitigated or prevented by one or more items relied on for safety. The review may encompass examination of a selected number of lower risk chemical safety-related accident sequences not contained in the ISA summary to validate the risk threshold criteria used by the applicant in assigning sequences to the ISA summary.

6.5.2.2 Items Relied on for Safety and Management Measures

The staff reviews the chemical process safety controls to ensure that adequate controls have been identified and will be reliable and available in accordance with criteria in 6.4.3.2. The review assures the adequacy of controls for all unmitigated sequences identified in the ISA. The chemical process safety review should be coordinated with the ISA (SRP Section 3.0), Nuclear Criticality Safety (SRP Section 5.0), Fire Safety (SRP Section 7.0), Emergency Management (SRP Section 8.0), Environmental Protection (SRP Section 9.0) and Management Measures (SRP Section 11.0) reviewers to achieve thoroughness.

For items relied on for safety the applicant should apply the graded approach, i.e. provide controls or management measures commensurate with risk. For example, the applicant should consider reliance on passive controls over active systems and consider defense-in-depth. To reduce common mode failures, the applicant should favor design features that utilize independent sources of motive force for items like: control actuators, jet pumps, eductors, and ejectors. Fail-safe controls are preferred unless safety concerns preclude this approach. The graded approach should also be applied to management measures.

If procedures are used by an applicant as an item relied on for safety for higher risk accident sequences, verify for chemical process safety that the applicant identifies the importance of procedure adherence for both worker and/or public safety. Verify the same for alarm response procedures that require operators to initiate actions to prevent or mitigate any higher risk accident sequences.

6.5.2.3 Requirements for New Facilities or New Processes at Existing Facilities

The staff reviews information required in 6.4.3.3 Acceptance Criteria, using the review methods in 6.5.2.1 and 6.5.2.2.

When the safety evaluation is complete, the staff reviewer documents the safety review in a Safety Evaluation Report (SER) for chemical process safety, as described in section 6.6.

6.6 EVALUATION FINDINGS

The reviewer verifies that the information submitted by the applicant is in accordance with 10 CFR Part 70. In the staff's Safety Evaluation Report (SER), the reviewer documents the basis for determining the adequacy of the application with respect to chemical process safety. The reviewer also describes the applicant's approach to ensuring the availability and reliability of the controls. Based on the review of the application, statements and conclusions of the following type should be included in the staff's draft SER as appropriate:

> Based on the review of the license application, the NRC staff concluded that the applicant has adequately described and assessed accident consequences with significant chemical consequences that could result from the handling, storage, or processing of special nuclear material. A hazard analysis has been conducted that identified and evaluated those chemical process hazards and potential accidents and established safety controls to ensure safe facility operation. To ensure that the limits in 10 CFR Part 70 are met, the applicant will ensure that controls are maintained available and reliable when required to perform their safety functions. The staff has reviewed these safety controls and the applicant's plan for managing chemical process safety and finds them acceptable.
>
> The staff concludes that the applicant's plan for managing chemical process safety and the chemical process safety controls meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public will be protected.

In cases where the SER is drafted in advance of resolving all outstanding chemical process safety issues, the reviewer documents the review as described above and includes a list of open issues that require resolution prior to the staff finding of reasonable assurance. For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the chemical process safety significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

6.7 REFERENCES

Chemical Manufacturers Association, *"Responsible Care®, Process Safety Code of Management Practices"*, Washington, 1990.

Center for Chemical Process Safety, *"Guidelines for the Technical Management of Chemical Process Safety"*, American Institute of Chemical Engineers, New York, 1989, Chapter 11, as revised.

Code of Federal Regulations, Title 10, Part 70*, "Domestic Licensing of Special Nuclear Material"*, U.S. Government Printing Office, Washington, D.C., as revised.

Code of Federal Regulations, Title 29, Part 1910.119, *"Process Safety Management of Highly Hazardous Chemicals"*, U.S. Government Printing Office, Washington, D.C., as revised.

Manual Chapter 2603, *"Inspection of the Nuclear Chemical Process Safety Program at Fuel Cycle Facilities"*, as revised.

Memorandum of Understanding between the Nuclear Regulatory Commission and the Occupational Safety and Health Administration, "*Worker Protection at NRC-Licensed Facilities",* Federal Register No. 53, October 31, 1988.

NUREG/CR-6410, *"Nuclear Fuel Cycle Facility Accident Analysis Handbook"*, 1998.

NUREG-1601, *"Chemical Process Safety at Fuel Cycle Facilities"*, 1997.

NUREG/CR-6481, *"Review of Models Used for Determining Consequences of UF_6 Release"*, as revised.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

7.0 FIRE SAFETY

7.1 PURPOSE OF REVIEW

The purpose of this review is to determine with reasonable assurance that an applicant has appropriately analyzed the fire and explosion risks, which could effect the safety of licensed materials and thus present an increased radiological risk, and provided mitigative systems and controls to protect the workers, the public health and safety, and the environment.

7.2 RESPONSIBILITY FOR REVIEW

Primary: Fire Protection Reviewer

Secondary: Criticality Reviewer
Environmental Reviewer
Chemical Safety Reviewer
Physical Security Reviewer

Supporting: Region or Fuel Facility Inspection Staff and Resident Inspector

7.3 AREAS OF REVIEW

The regulation, 10 CFR 70.62, requires that each licensee establish and maintain a safety program that demonstrates compliance with the performance requirements in §70.61. A separate fire safety program is not required, however, the licensee shall demonstrate that the facility's safety function includes the following (as appropriate):

Fire Safety Management: This includes safety organization, engineering review, fire prevention, inspection, testing, and maintenance, prefire plans, and qualifications, drills, and training.

Fire Risk Identification: This includes a Fire Hazards Analysis (FHA) and an Integrated Safety Analyses (ISA).

Facility Design: This includes information on building construction, fire areas, life safety, ventilation, and electrical system design. Consideration of competing requirements among fire safety and security, criticality, and environmental concerns should be accounted for.

Process Fire Safety: This involves design consideration to prevent an accident or mitigate the consequences from using process chemicals, combustible metals, flammable and combustible liquids and gasses, high temperature equipment, hot cells and glove boxes, and laboratories.

Fire Protection Systems: This includes the specified application of fire detection, alarm, and suppression systems, portable extinguishers, water supply, and emergency response organization.

7.4 ACCEPTANCE CRITERIA

An applicant that has met the following acceptance criteria, or has provided an acceptable alternative, should be considered to have an acceptable fire safety function.

7.4.1 Regulatory Requirements

The regulatory basis for the review should be the general and additional contents of an application as required by 10 CFR 70.22 and 70.65. In addition, the fire safety review should be conducted to provide reasonable assurance of compliance with 10 CFR 70.61, 70.62, and 10 CFR 70.64 for new facilities or new processes.

7.4.2 Regulatory Guidance

Relevant regulatory guidance for fire safety includes:

1) NUREG/CR-6410, *"Nuclear Fuel Cycle Facility Accident Analysis Handbook,"* 1998.

2) NUREG-1513, *"Integrated Safety Analysis Guidance Document."* latest edition.

7.4.3 Regulatory Acceptance Criteria

The acceptability of the application and the ISA summary will be based on the NRC staff's review of the applicant's commitments to control and mitigate fire hazards. The staff will focus on an application that is risk informed, has addressed maintaining an acceptable level of nuclear safety, and demonstrates that an applicant is prepared to react quickly and safely to extinguish fires when they occur. An applicant may use a graded approach for defining fire safety, but sufficient documentation and commitments must be made to assure the protection of workers, the public, and the environment from fire events.

These criteria may be incorporated in the information supplied to satisfy SRP Section 3.0 (ISA) or other sections of this SRP with references provided (information need not be repeated). The fire safety reviewer reviews the application, ISA summary and other ISA documentation as needed with respect to these acceptance criteria regardless of where the information appears.

Nationally recognized codes and standards are used to assure fire safety. These include, but are not limited to, the National Fire Protection Association (NFPA) National Fire Codes, Factory Mutual (FM) Data Sheets and Approval Guide, Underwriters Laboratories (UL) Standards and Building Material Directory, American National Standards Institute (ANSI) Standards, and

American Society for Testing Materials (ASTM) Standards. The NRC staff will review the application against the following acceptance criteria:

7.4.3.1 Fire Safety Management Measures

An adequate application documents how fire safety is administered and assured at the licensed facility. The application should reflect a commitment to assure the items relied upon for safety as identified in the Integrated Safety Analysis (ISA) summary, Section 3.0, are available and reliable, fire safety awareness among employees is maintained, transient ignition sources and combustibles are controlled, and the facility maintains a readiness to extinguish or limit the consequences of fire. The application will be reviewed by a staff fire protection engineer and will address fire safety management measures. These measures are unique to fire safety and are therefore not included in the acceptance criteria for SRP Section 11, Management Measures.

An adequate application identifies a senior level manager who has the authority and staff to ensure that fire safety receives appropriate priority. A Plant or Fire Safety Review Committee staffed by different discipline managers should integrate plant modifications. Day-to-day supervision of fire safety should be by an individual with sufficient practical fire safety experience (that is described in the application) in nuclear facilities.

The Standard for Fire Protection for Facilities Handling Radioactive Materials, NFPA 801, specifies the following fire safety management measures: fire prevention, inspection, testing, and maintenance of fire protection systems, emergency response organization qualifications, drills, and training, and prefire plans. An adequate application documents the fire safety management measures in sufficient detail to identify their relationship to, and functions for, normal operations, anticipated (off-normal) events, and accident safety (i.e., items relied on for safety).

7.4.3.2 Fire Risk Analysis

Knowing the fire risk allows a licensee to apply the appropriate level of fire protection to assure the safety of workers, the public, and the environment. To be risk informed, a licensee should conduct Fire Hazards Analyses (FHA) for high risk facilities. The FHA should develop bounding credible fire scenarios for each process fire area with significant fire loading, then assess or model the consequences of an unmitigated fire. NFPA 801 provides further guidance that is acceptable to the NRC staff for conducting FHAs. With respect to fire safety, the ISA summary is acceptable if the credible facility fire hazards (e.g., from the FHA) are identified for each process area, and information is provided detailing how that fire hazard was considered and addressed (i.e., the management measures and/or items relied on for safety) for each process such that the performance requirements in §70.61 are satisfied. A summary of the FHA is acceptable if it includes a description, by fire area, of the fuel loading, fire scenarios, methods of consequence analysis, the consequences, and a description of the mitigative controls.

7.4.3.3 Facility Design

NFPA 801 specifies facility design considerations that are acceptable to the NRC staff. Building construction, fire area determination, electrical installation, life safety, ventilation, drainage, and lightning protection are a few of the areas covered. An adequate application documents the fire safety considerations used in the general facility design of the licensed facilities. The following are other specific areas of concern:

Criticality: Criticality concerns may exclude water extinguishing systems from process areas. However during major fire events, the fire may overcome the extinguishing capability of portable extinguishers and hose lines may be needed. Consideration should be given to total flooding gaseous systems in water exclusion areas with significant fire risks. An adequate application should address the methodology used for extinguishing fires in water exclusion areas. The staff's fire safety and criticality specialist will review for adequacy.

Environmental Concerns: Thousands of gallons of fire water can be contaminated with nuclear material during a fire event. Diked areas and drainage of process facilities need to be properly sized to accommodate this run-off. The amount of runoff can be calculated using guidance in NFPA 801. An adequate application documents fire water run-off containment. The staff's fire safety and environmental specialists will review for adequacy.

Physical Security Concerns: Buildings and facilities should be designed to provide safe egress in the event of a fire, chemical, or radiological emergency. Physical security of SNM may inadvertently institute controls that delay worker egress and fire fighter access. Physical security procedures need to allow off-site fire departments quick and efficient access to the fire emergency. NFPA 801 specifies design features acceptable to the NRC and an adequate application documents the criteria used for worker egress and procedures for firefighter access. The staff's fire safety and physical security specialists will review for adequacy.

7.4.3.4 Process Fire Safety

Many hazardous chemicals used by fuel cycle facilities contribute to the fire hazard. The licensee should identify these chemicals and their effect on fire safety. In fire areas containing radiological material, NFPA 801 provides design criteria that is acceptable to the NRC staff for laboratories, high temperature equipment, hots cells, and glove boxes. The staff's fire safety and chemical safety specialists will review the application for adequacy.

The following are a few of the more common hazardous substances used at fuel cycle facilities:

Anhydrous Ammonia: Explosive, flammable, and toxic gas used to make hydrogen.
Fluorine: Reacts violently with organic material or metal powders and water vapor.
Hydrogen: Explosive and flammable gas used in reduction processes.
Hydrogen Peroxide: Off-gases hydrogen and oxygen, incompatible with some extinguishers.
Nitric Acid: Nitrates organic material, lowering the ignition temperature of combustibles.
Sulfuric Acid: Absorbs water from organic material in an exothermic reaction, causing ignition.
Zirconium: Combustible metal that burns at elevated temperatures.

7.4.3.5 Fire Protection and Emergency Response

The application should document the fire detection, alarm, and suppression systems and emergency response organizations provided for licensed facilities. The ISA summary (see SRP Section 3.0) should identify and list the items relied upon for fire safety. NFPA 801 provides criteria that is acceptable to the NRC staff for the design, installation, testing, and maintenance of the fire protection systems and the requirements for an effective emergency response organization. An adequate application should describe the fire protection provided in all process areas.

Facilities with significant fire risks may need a fire emergency response team in accordance with NFPA 600, “Industrial Fire Brigades.” If the off-site fire department is depended upon for plant safety, periodic training with the fire department is necessary to become familiar with facility access procedures, plant layout, and pre-fire plans. A memorandum of understanding (MOU) between the applicant and the fire departments may be necessary to define the protection required.

7.5 REVIEW PROCEDURES

7.5.1 Acceptance Review

During the acceptance review, the primary reviewer evaluates the application for completeness as required by 10 CFR Part 70 regarding fire safety for fuel cycle facilities and whether necessary criteria discussed in Section 7.3 “Areas of Review,” have been addressed. If significant deficiencies are identified in the application, the application should be returned or additional information should be requested before the start of the safety evaluation.

7.5.2 Safety Evaluation

During the Safety Evaluation, the primary and secondary reviewers evaluate the adequacy of the application to comprehensively describe the fire safety of the licensed activity as covered in Section 7.3 “Areas of Review” and the commitments made to the criteria specified in Section 7.4 “Acceptance Criteria.” The staff may request the applicant or licensee to provide additional information or modify the submittal to meet the acceptance criteria.

Reviewers should note that NFPA 801 uses "administrative control" in a different sense than Part 70 and elsewhere in this SRP. In Part 70 an administrative control, which is a subset of items relied on for safety, is the human action necessary to meet safety performance requirements. It is supported by management measures (training, QA, procedures, ...) that ensure the action will be taken if needed. In NFPA 801, administrative controls are the training, qualifications, procedures, etc. behind the human action. These elements are "Management Measures" in Part 70.

7.6 EVALUATION FINDINGS

The staff’s review should verify that sufficient information has been provided in the license application to satisfy the intent of 10 CFR Part 70 requirements relating to the overall safety

program and is consistent with the fire safety criteria in this SRP. On the basis of this information, the staff should be able to evaluate the application in meeting the appropriate criteria. The staff will document the fire safety review as follows.

The applicant has established a Fire Protection Program meeting the acceptance criteria of the SRP. The program includes a Plant Safety Review Committee responsible for integrating modifications to the facility and a Fire Safety Manager responsible for the day to day program implementation. Fire prevention, inspection, testing, and maintenance of fire protection systems, and the qualification, drills, and training of plant personnel are in accordance with applicable NFPA codes and standards. (Note: fire protection training requirements may be described in this section of the SRP or in SRP Section 11.3)

The applicant has conducted risk analysis in accordance with NFPA 801. The FHAs identified credible fire scenarios that bound the fire risk. The ISA used these scenarios and identified fire protection items important to safety. In particular, wet pipe sprinkling the process areas, isolating high temperature equipment within fire barriers, and a fire brigade meeting NFPA 600. An MOU with the fire department documents the protection required and the annual exercises. Procedures are in-place to allow efficient access by the fire department to plant process areas during fire emergencies.

Accordingly, the staff concludes that the applicant's description of fire safety complies with applicable NRC regulations and industry standards and can be implemented for the specific phases identified in the facility application.

7.7 REFERENCES

Code of Federal Regulations, 29 CFR 1910, “Occupational Safety and Health Standards.”

National Fire Protection Association, “National Fire Codes.”

U.S. Nuclear Regulatory Commission, Information Notice No. 92-14, ”Uranium Oxide Fires at Fuel Cycle Facilities,” February 21, 1992.

U.S. Nuclear Regulatory Commission, Information Notice No. 97-23, ”Evaluation and Reporting of Fires and Unplanned Chemical Reaction Events at Fuel Cycle Facilities,” May 7, 1997.

8.0 EMERGENCY MANAGEMENT

8.1 PURPOSE OF REVIEW

The review should determine if the applicant has established, before the start of operations, adequate emergency management facilities and procedures to protect the public, the workers, and the environment.

An emergency plan is required when an evaluation shows that the maximum dose to a member of the public offsite due to a release of radioactive materials would exceed 1 rem (0.01 Sv) effective dose equivalent. This section applies to facilities authorized to possess enriched uranium (U) or plutonium (Pu) for which a criticality accident alarm system is required, uranium hexafluoride (UF_6) in excess of 50 kg (110 lb) in a single container or 1000 kg (2200 lb) total, or in excess of 2 Ci of Pu in unsealed form or on foils or plated sources.

Emergency capability is incorporated into the baseline design criteria (BDC) of 10 CFR Part 70, as revised, and is intended to ensure control of licensed material, evacuation of personnel, and availability of emergency facilities.

8.2 RESPONSIBILITY FOR REVIEW

Primary: Assigned LIB staff

Secondary: Licensing Project Manager

Supporting: Regional Emergency Preparedness Inspector
ISA Reviewer
Fuel Facility Inspection staff

8.3 AREAS OF REVIEW

The NRC staff should review the applicant's submittal for an acceptable level of evidence of planning for emergency preparedness directed at situations involving real or potential radiological hazards. The review should address those design features, facilities, functions, and equipment that may affect some aspect of emergency planning or the capability of an applicant to cope with plant emergencies. In addition, the review should address coordination with offsite organizations. The staff should either review the emergency plan made in accordance with 10 CFR 70.22(i)(1)(ii) and with the guidance contained in the acceptance criteria below, or should review the applicant's evaluation that an emergency plan is not needed in accordance with 10 CFR 70.22(i)(1)(i).

The NRC staff reviewer should address the material presented, as described below.

8.3.1 Evaluation That No Emergency Plan is Required

If the applicant submits an evaluation, to demonstrate that an emergency plan is not required, the staff should review the evaluation against 10 CFR 70.22(i)(1)(i), and NUREG-1140, "A Regulatory Analysis of Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees." NUREG/CR-6410, "Nuclear Fuel Cycle Facility Accident Analysis Handbook," also contains useful information. Areas to be evaluated should include the following:

3. A description of the facility,
4. Types of materials used, including both radioactive material and hazardous chemicals,
5. Types of accidents,
6. Detection of accidents,
7. Site specific information used to support the evaluation, and
8. An evaluation of the consequences, both onsite and offsite, of accidents including radioactive and hazardous chemicals. The evaluation shows that the maximum dose to a member of the public offsite due to a release of radioactive materials would not exceed 1 rem (0.01 Sv) effective dose equivalent or an intake of 2 milligrams of soluble uranium in accordance with 10 CFR 70.22(i)(1)(i).
9. The evaluation should address one or more of the factors provided in 10 CFR 70.22(i)(2).

8.3.2 Emergency Plan

If the applicant submits an emergency plan, the staff should evaluate the emergency management program against 10 CFR 70.22(i)(1)(ii) and Regulatory Guide 3.67, "Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities," which provides a standard format and content for an emergency plan. Elements in the emergency plan to be reviewed should include the following:

1. Facility description (including both onsite and offsite emergency facilities),
2. Types of accidents,
3. Classification of accidents,
4. Detection of accidents,
5. Mitigation of consequences (and safe shutdown),
6. Assessment of releases (both radioactive materials and hazards chemicals),
7. Responsibilities of licensee,
8. Notification and coordination,
9. Information to be communicated and parties to be contacted,
10. Training,
11. Safe shutdown (recovery and plant restoration),
12. Exercises (and drills),
13. Hazardous chemicals inventories and locations, and
14. Responsibilities for developing and maintaining the emergency program and its procedures.

8.4 ACCEPTANCE CRITERIA

8.4.1 Regulatory Requirements

10 CFR Part 70.22(i)(1)(i) specifies when an emergency plan does not have to be submitted to the NRC and, if an emergency plan is required to be submitted, 10 CFR Part 70.22(i)(3), contains the information that must be included in the emergency plan.

10 CFR Part 70.64(a)(6) requires that applicants address the control of licensed material, evacuation of personnel, and availability of emergency facilities for the design of new facilities.

8.4.2 Regulatory Guidance

Regulatory guidance for preparing an emergency plan includes:

1. Regulatory Guide 3.67, "*Standard Format and Content for Emergency Plans for Fuel Cycle and Materials Facilities,"* January 1992.

2. NUREG-1140, “A Regulatory Analysis of Emergency Preparedness for Fuel Cycle and Other Radioactive Materials,” January 1988.

3. NUREG/CR-6410, “Nuclear Fuel Cycle Facility Accident Analysis Handbook,” 1998.

8.4.3 Regulatory Acceptance Criteria

8.4.3.1 Evaluation That No Emergency Plan Is Required

The adequacy of the evaluation that no emergency plan is required should be evaluated by the reviewer against the requirements in 10 CFR Part 70.22(i)(2), and the specific criteria given in the following sections of the SRP. This evaluation should be acceptable if the regulatory requirements and the following criteria are met:

8.4.3.1.1 Facility Description

The evaluation includes a description of the facility and site, the area near the site, and the licensed activities conducted at the facility sufficient to support the evaluation. The description includes the following:

1. A detailed drawing of the site showing (1) onsite and near offsite (within 1 mile) structures with building numbers and labels, (2) roads and parking lots onsite and main roads near the site, (3) site boundaries, showing fences and gates, (4) major site features, (5) water bodies within approximately 1 mile, and (6) the location(s) of nearest residents.

2. The stack heights, typical stack flow rates, and the efficiencies of any emission control devices.

3. A general description of licensed and other major activities conducted at the facility, and the type, form, and quantities of radioactive and other hazardous material normally onsite.

8.4.3.1.2 Types of Accidents

The evaluation describes each type of accident identified by the ISA that has the maximum offsite consequences exceeding the limit of 10 CFR 70.22(i)(1)(i). The description includes:

1. The process and physical location where it could occur,

2. Complicating factors and possible onsite and offsite consequences, including non-radioactive hazardous material released,

3. The accident sequence that has the potential for the greatest radiological and toxic chemical impact.

8.4.3.1.3 Detection of Accidents

The evaluation described for each type of accident identified the following:

1. The means of detecting the accident,

2. The means of detecting any release of radioactive or other hazardous material,

3. The means of alerting the operating staff, and

4. The anticipated response of the operating staff.

8.4.3.1.4 Evaluation of Maximum Public Exposure

In order to demonstrate that no emergency plan is required, an applicant may either (1) request that its total possession limit for radioactive material be reduced below the emergency plan threshold in 10 CFR 70.22(i)(1), or (2) perform a site specific evaluation that demonstrates maximum public exposure is less than the limits in 70.22(i)(1)(i).

The evaluation should include a description of the following information sufficient to allow for independent verification:

1. Type of accident (e.g., fire, exposure, chemical release, nuclear criticality),
2. Location of accident,
3. Maximum source term,
4. Solubility of material,
5. Facility design or engineered safety features in the facility and the proposed release fraction,
6. Location and distance of nearest member of the public to the facility,

7. Dose model used and the process used to verify the reliability of the model and validity of the assumptions,
8. Assumed worst case weather condition, and
9. Maximum calculated dose to a member of the public at the facility boundary.

The evaluation should include a list and a description of the factors in 10 CFR 70.22(i)(2) considered in evaluating maximum dose to members of the public. The applicant should demonstrate why the factors used in the evaluation are appropriate when compared to the factors in NUREG-1140. If the factors and evaluation show that the maximum dose to a member of the public offsite due to a release of radioactive materials could not exceed 1 rem (0.01 Sv) effective dose equivalent or the intake of soluble uranium of 2 milligrams, no emergency plan is required in accordance with 10 CFR 70.22(i)(1)(i).

8.4.3.2 Emergency Plan

The adequacy of the proposed emergency plan should be evaluated by the reviewer against the requirements in 10 CFR Part 70.22(i)(3), and the specific criteria given in the following sections of the SRP. The applicant's emergency plan should be acceptable, if the regulatory requirements and the following criteria are met:

8.4.3.2.1 Facility Description

8.4.3.2.1.1 Operational Facilities

The emergency plan should include a description of the facility and site, the area near the site, and the licensed activities conducted at the facility sufficient to support emergency management activities. The description should include the following:

1. A detailed drawing of the site showing:

    a. onsite and near offsite (within 1 mile) structures with building numbers and labels,
    b. roads and parking lots onsite and main roads near the site,
    c. site boundaries, showing fences and gates,
    d. major site features, and
    e. water bodies within approximately 1 mile.

2. A general area map (approximately 16.09 km [10-mile] radius), a United States Geological Survey topographical quadrangle (7 ½ minute series; including the adjacent quadrangle(s) if site is located less than 1.609 km (1 mile) from the edge of the quadrangle), and a map or aerial photograph indicating onsite structures and near-site structures (about 1.609 km [1-mile] radius). The map should include the location of sensitive facilities near the site such as hospitals, schools, nursing homes, nearest residents, fire department, prisons, and environmental sampling locations, and other structures and facilities important to emergency management.

3. The stack heights, typical stack flow rates, and the efficiencies of any emission control devices.

4. A general description of licensed and other major activities conducted at the facility, and the type, form, and quantities of radioactive and other hazardous materials normally onsite, by location (use and storage) and building, and hazardous characteristics (exposure rates, pH, temperature, and other characteristics) important to emergency management.

5. Certification that the applicant has met responsibilities under Emergency Planning and Community Right To Know Act of 1986, Title III, Public Law 99-499, in accordance with 10 CFR 70.22(i)(3)(xiii).

8.4.3.2.2 Onsite and Offsite Emergency Facilities

The emergency plan should include a list and description of onsite and offsite facilities that could be relied upon in the event of an emergency. The description should include the following:

1. A list and description of both onsite and offsite emergency facilities by location and purpose of the facility.

2. A description of emergency monitoring equipment which is available for personnel and area monitoring, as well as that for assessing the release of radioactive or hazardous materials to the environment.

3. A description of the onsite and offsite services which support emergency response operations. The following are included:

   a. decontamination facilities,
   b. medical treatment facilities,
   c. first aid personnel,
   d. fire fighters,
   e. law enforcement assistance, and
   f. ambulance services.

4. In addition, the applicant should have emergency facilities, equipment, and resources, which are ready to support emergency response operations, including the following:

   a. Facilities of adequate size and appropriate location that are designated, equipped, and ready for emergency use,

   b. Adequate backup facilities required by the emergency plan and supporting documents that are available and ready for use,

   c. Appropriate equipment and supplies necessary to support emergency response activities that are accessible during accident conditions,

   d. Emergency equipment that is inventoried, tested, and serviced on a periodic basis to ensure accountability and reliability,

e. Sufficient reliable primary and backup communications channels that are available to accommodate emergency needs,

f. Offsite emergency resources and services that are identified, and are ready to ensure their timely mobilization and use,

g. Operational engineering information, such as current as-built drawings and procedures, that are readily available in the emergency facilities,

h. Sufficient equipment for personnel protection and monitoring, and

i. Systems in place to alert onsite and offsite personnel in the event of an emergency.

8.4.3.2.3 Types of Accidents

The emergency plan should include a description for each accident identified by the ISA for which protective actions may be needed. The description should include:

1. The process and physical location(s) where the accidents could occur,

2. Complicating factors and possible onsite and offsite consequences, including nonradioactive hazardous material releases that could impact emergency response efforts,

3. The accident sequence that has the potential for the greatest radiological and toxic chemical impact, and

4. Figure(s) projecting dose and toxic substance concentration as a function of distance and time for various meteorological stability classes.

8.4.3.2.4 Classification of Accidents

1. The emergency plan classification system should include the following two classifications:

   - "Alert": Events that may occur, are in progress, or have occurred that could lead to a release of radioactive material or hazardous chemicals incident to the process, but the release is not expected to require a response by an offsite response organization to protect persons offsite.

   - "Site area emergency": Events that may occur, are in progress, or have occurred that could lead to a significant release of radioactive material or hazardous chemicals incident to the process that could require a response by offsite emergency response organizations to protect persons offsite.

2. For each accident in the emergency plan, the classification (alert or site area emergency) that is expected for each accident is identified.

3. The emergency plan should specify emergency action levels (EALs) at which an alert or site area emergency will be declared. EALs are specific conditions that require emergency response measures to be performed. The applicant's EALs are consistent with Appendix A of Regulatory Guide 3.67 and are compared with the Environmental Protection Agency's Protective Action Guides (EPA 400-R-92-001, May 1992 Revision). Transportation accidents more than 1 mile from the facility are not classified.

4. The emergency plan should designate the personnel positions and alternates with the responsibility for accident classification during normal and back shift hours.

8.4.3.2.5 Detection of Accidents

The emergency plan should describe, for each type of accident identified, the following:

1. The means of detecting the accident,

2. The means of detecting any release of radioactive or other hazardous material,

3. The means of alerting the operating staff, and

4. The anticipated response of the operating staff.

8.4.3.2.6 Mitigation of Consequences

1. The emergency plan should describe for each accident identified, adequate measures and equipment for safe shutdown and for mitigating the consequences to workers onsite and offsite as well as to the public offsite.

2. For impending danger from an accident initiator, the application should describe the following:

   a. The criteria that will be used to determine whether a single process or the entire facility will be shut down,

   b. The steps that will be taken to ensure a safe orderly shutdown of a single process or the entire facility,

   c. The approximate time required to accomplish a safe shutdown of processes, and

   d. The compensatory measures required for safety during the shutdown period following an accident.

8.4.3.2.7 Assessment of Releases

1. The emergency plan should describe the applicant's procedures to be used to promptly and effectively assess the release of radioactive material or hazardous chemicals associated with the processing of radioactive material. The description includes:

   a. The procedures for estimating or measuring the release rate or source term,

   b. Valid computer codes used to project doses or concentrations to the public or environment and associated assumptions, along with adequate justifications to show the validity of the assumptions,

   c. The types, methods, frequencies, implementation time, and other details of onsite and offsite sampling and monitoring that will be performed to assess a release of radioactive material or hazardous chemicals, and

   d. Method for assessing collateral damage to the facility, especially safety controls.

2. The emergency plan should describe the applicant's procedure for validating any code used to assess releases of radioactive material or hazardous chemicals.

8.4.3.2.8 Responsibilities

The emergency plan should describe the emergency response organization and administration which ensures effective planning, implementation, and control of emergency preparedness activities and meet the following criteria:

1. The organizational structure and chain of command are clearly defined,

2. Staffing and resources are sufficient to accomplish assigned tasks,

3. Responsibilities and authority for each management, supervisory, and professional position are clearly defined. Responsibility is assigned for the coordination of onsite and offsite radiation/hazardous material emergency response preparedness,

4. Interfaces with supporting groups, both onsite and offsite, are clearly defined,

5. Mutual cooperation agreements exist with local agencies such as fire, police, ambulance/rescue, and medical units,

6. Plant management measures include audit and assessment (SRP Section 11.5) of emergency preparedness to ensure site readiness to handle emergencies and to identify and correct problems,

7. The onsite emergency response organization as described provides reasonable assurance of effective command and control of the site during the assessment, mitigation, and recovery phase of an accident,

8. The emergency public information staff provides advance and ongoing information to the media and public on subjects that would be discussed during an emergency, such as radiation hazards, chemical hazards, site operation, and site emergency plans, and

9. The schedule of emergency preparedness procedure development provides for availability of procedures to support start-up and operation of new processes/facilities onsite.

8.4.3.2.9 Notification and Coordination

1. The emergency plan should provide reasonable assurance that emergency notification procedures will enable the emergency organization to correctly classify emergencies, notify emergency response personnel, and initiate or recommend appropriate actions in a timely manner, based on the following:

   a. Classification of emergency events are based on the current emergency plan.

   b. Notification procedures minimize distractions of shift operating personnel and include concise, preformatted messages. Appropriate follow-up messages to offsite authorities are issued in a timely manner.

   c. Information on the nature and magnitude of the hazards are made available to appropriate emergency response personnel.

   d. Radiological and chemical source term data are available to the command post, technical support center, emergency operation center, and appropriate State personnel, in cooperation with NRC.

   e. When available, offsite field monitoring data are logged, compared with source term data, and used in the protective action recommendation process.

   f. Protective Action Guides are available and used by appropriate personnel in a timely manner.

   g. The emergency public information program ensures timely dissemination of accurate, reliable, and understandable information.

   h. Systems are in place, if required, to alert, notify, and mobilize onsite and offsite response personnel in the event of an emergency.

   i. Notification and coordination with responsible parties when some personnel, equipment, and facility components are not available.

2. The emergency plan should describe how and by whom the following actions will promptly and effectively be taken:

   a. Decision to declare an alert or site area emergency,

b. Activation of onsite emergency response organization during all shifts,

c. Prompt notification of offsite response authorities that an alert or site area emergency has been declared, including the licensee's initial recommendation for offsite protective actions (normally within 15 minutes),

d. Notification to the NRC Operations Center (as soon as possible and, in any case, no later than one hour after a declared emergency),

e. Decision on what onsite protective actions to initiate,

f. Decision on what offsite protective actions to recommend,

g. Decision to request support from offsite organizations, and

h. Decision to terminate the emergency or enter recovery mode.

8.4.3.2.10 Information To Be Communicated

The emergency plan should describe the information to be communicated during an emergency including the following:

1. A standard reporting checklist to facilitate timely notification,

2. The types of information to be provided concerning facility status, radioactive or hazardous chemical releases, and protective action recommendations,

3. A description of preplanned protective action recommendations to be made to each appropriate offsite organization,

4. The offsite officials to be notified, as a function of the classification of the event,

5. The recommended actions to be implemented by offsite organizations for each accident treated in the emergency plan.

8.4.3.2.11 Training

The emergency plan should include an adequate training program for onsite and offsite emergency response personnel to ensure knowledge of the emergency plan, assigned duties, and effectively respond to an actual emergency. The description includes:

1. The topics and general content of training programs used for training the onsite and offsite emergency response personnel to satisfy the objectives described above,

2. The administration of the training program, including responsibility for training, the positions to be trained, the schedules for training, the frequency of retraining, use of team training and the estimated number of hours of initial training and retraining,

3. The training to be provided on the use of protective equipment such as respirators, protective clothing, monitoring devices, and other equipment used in emergency response,

4. The training program for onsite personnel who are not members of the emergency response staff, and

5. The instructions and tours that will be offered to fire, police, medical, and other emergency personnel to the extent necessary commensurate with the results of the ISA.

8.4.3.2.12 Safe Shutdown (recovery and plant restoration)

The emergency plan should describe the plans for adequately restoring the facility to a safe status after an accident and recovery after an emergency. The description should include:

1. Appropriate methods and responsibilities for assessing the damage to and the status of the facility's capabilities to safely control radioactive material or hazardous chemicals associated with the process,

2. Procedures for promptly determining the actions necessary to reduce any ongoing releases of radioactive or other hazardous chemicals and to prevent further incidents,

3. Provisions for promptly and effectively accomplishing required restoration action, and

4. Describing the key positions in the recovery organization.

8.4.3.2.13 Exercises and Drills

The emergency plan should commit to conducting exercises and drills in a manner that demonstrates the capability of the organization to plan and perform an effective response to an emergency. An adequate plan should demonstrate the following:

1. Task-related knowledge is demonstrated through periodic participation by all qualified individuals for each position in the emergency response organization,

2. Drill performance is assessed against specific scenario objectives, using postulated accidents, that adequately test personnel, equipment, and resources, including previously identified weaknesses,

3. Effective player, controller, evaluator, and observer pre-drill briefings are conducted,

4. Scenario data and exercise messages provided by the controllers effectively maintain the time line and do not interfere with the emergency organization's response to exercise scenario events, except where safety considerations are involved,

5. Trained evaluators are used to identify and record participant performance, scenario strengths and deficiencies, and equipment problems,

6. Prestaging of equipment and personnel is minimized to realistically test the activation and staffing of emergency facilities,

7. Critiques are conducted in a timely manner and include a follow-up plan for correcting identified weaknesses and improving training effectiveness,

8. Emergency drills demonstrate that resources are effectively used to control the site, to mitigate further damage, and to control radiological/chemical releases, to perform required onsite activities under simulated radiation/airborne and other emergency conditions, to provide accurate assessments and status during an accident, and to initiate recovery,

9. Emergency drills demonstrate personnel protection measures, including controlling and minimizing hazards to individuals during events such as fires, medical emergencies, mitigation activities, search and rescue, and other similar events,

10. The emergency drill demonstrates that onsite communications effectively support emergency response activities,

11. The emergency drill demonstrates that the emergency public information organization disseminates accurate, reliable, timely, and understandable information,

12. Provisions are made for conducting quarterly communications checks with offsite response organizations, and

13. Offsite organizations are invited to participate in the biennial onsite exercise that tests the major elements of the emergency plan and response organizations.

8.4.3.2.14 Responsibilities for Developing and Maintaining Current the Emergency Program and Its Procedures

The emergency plan should describe the responsibilities for developing and maintaining the emergency program and its procedures. The description should include:

1. The means for ensuring that the revisions to the emergency plan and the procedures which implement the emergency plan are adequately prepared, kept up to date normally (within 30 days of any changes), and distributed to all affected parties including the NRC, and

2. The provisions for approval of the implementing emergency procedures, making and distributing changes to the procedures, and ensuring that each person responsible for

an emergency response function has immediate access to a current copy of emergency procedures. Provisions for approval of changes to the emergency plan and the procedures and those individuals authorized to make these changes are clearly stated.

3. Procedures for allowing offsite response organizations 60 days to comment on the emergency plan before submitting it to the NRC, and to provide NRC any comments received within 60 days along with the plan.

4. Procedures for modifying the emergency plan in accordance with 10 CFR 70.32(i).

8.5 REVIEW PROCEDURES

8.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 8.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

8.5.2 Safety Evaluation

After determining that the application is acceptable for review in accordance with Section 8.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 8.4. If during the course of the safety evaluation, the primary reviewer determines the need for additional information, the primary reviewer should coordinate a request for additional information with the licensing project manager.

8.5.2.1 Evaluation That No Emergency Plan Is Required

The primary reviewer should verify that the evaluation is consistent with the potential accident sequences described in the ISA. The ISA reviewer and the primary reviewer should coordinate to assure the resolution of any issues concerning the evaluation relative to ISA information. The final step for the primary reviewer should be to prepare a safety evaluation report (SER) in accordance with Section 8.6 which either agrees with the applicant's conclusion that no emergency plan is required or indicates that the staff does not accept the applicant's evaluation and recommends that an emergency plan be required by the applicant.

8.5.2.2 Emergency Plan

After it is determined that an acceptable application containing an emergency plan has been received from the applicant, the primary reviewer should conduct a complete review and determine its acceptability in accordance with Section 8.4.3.2. The reviewer should verify that emergency planning is consistent with the potential accident sequences described in the ISA. The ISA reviewer and emergency plan reviewer should coordinate to assure the resolution of any issues concerning the emergency plan relative to ISA information.

Although the bulk of this information should be found in the Emergency Management program section of the licensee's submittal, the primary and secondary reviewers should gain familiarity

with the site, including the emergency planning zones, demography, land use, plant design and layout, and major accidents postulated by the applicant presented in relevant sections of the SAR. The primary and secondary reviewers should also gain familiarity with proposed radiation protection activities and other operational matters that interface with emergency plans, particularly the programs reviewed against SRP Chapters 4 and 11. Draft and final environmental statements for the proposed facility should be consulted. This information may be supplemented by a personal visit to the site by the reviewer and meetings with the applicant. Consultation with FEMA with respect to the relevant state and local government emergency response capabilities may also be necessary.

The final step for the primary reviewer should be to prepare an SER in accordance with Section 8.6, "Evaluation Findings."

8.6 EVALUATION FINDINGS

The primary reviewer writes an SER section addressing each topic reviewed under this SRP Chapter and explains why the NRC staff has reasonable assurance that the emergency management part of the application is acceptable. License conditions may be proposed to impose requirements where the application is deficient. The report includes a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.

The staff can document the evaluation as follows:

The staff has evaluated ..... [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] In accordance with 10 CFR 70.22(i), the licensee commits to maintaining and executing an emergency plan for responding to the radiological hazards resulting from a release of radioactive material and to any associated chemical process hazards. The NRC staff reviewed the emergency plan with respect to 10 CFR 70.22(i) and the acceptance criteria in 8.4.3 of the SRP. NRC staff determined that the applicant's emergency plan is adequate to demonstrate compliance with 10 CFR 70.22(i), including: (1) the plant is properly configured to limit releases of radioactive materials in the event of an accident, (2) a capability exists for measuring and assessing the significance of accidental releases of radioactive materials, (3) appropriate emergency equipment and procedures are provided onsite to protect workers against radiation and other chemical hazards that might be encountered following an accident, (4) a notification system has been established for notifying Federal, State, and local government agencies and recommending appropriate protective actions to protect members of the public, and (5) necessary recovery actions are established for returning the plant to a safe condition following an accident.

The requirements of the emergency plan are implemented through approved written procedures. Changes which decrease the effectiveness of the emergency plan may not be made without NRC approval. The NRC will be notified of other changes which do not decrease the effectiveness of the emergency plan within six months of the changes.

8.7 REFERENCES

1. U.S. Nuclear Regulatory Commission, *Part 30 Statements of Consideration and Emergency Preparedness for Fuel Cycle and Other Radioactive Material Licensees*, Federal Register 54, 14051, 1989.

2. NUREG/CR-6410, *Nuclear Fuel Cycle Accident Analysis Handbook*, U.S. Nuclear Regulatory Commission, 1998.

3. NUREG/BR-0150, Vol. 1, Rev. 4, *RTM-96 Response Technical Manual*, U.S. Nuclear Regulatory Commission, 1996.

4. EPA 400-R-92-001, *Manual of Protective Action Guides and Protective Actions for Nuclear Incidents*, Environmental Protection Agency, May 1992.

U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

9.0 ENVIRONMENTAL PROTECTION

9.1 PURPOSE OF REVIEW

The purpose of this review is to determine whether the applicant's proposed environmental protection measures are adequate to protect public health and the environment and comply with the regulatory requirements imposed by the Commission in 10 CFR Parts 20, 51, and 70. In addition, the staff will determine if the applicant submits an environmental report which is adequate for staff use in preparation of an Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) or an Environmental Impact Statement (EIS) pursuant to 10 CFR Part 51.

9.2 RESPONSIBILITY FOR REVIEW

Primary: Environmental Engineer/Scientist

Secondary: Licensing Project Manager

Supporting: Fuel Cycle Facility Inspector
Radiation Safety Reviewer
ISA Lead Reviewer

9.3 AREAS OF REVIEW

There are two distinct components of the application that require an environmental review. These are (1) the environmental report and (2) the description of environmental protection measures. The review of environmental protection measures includes a review of the applicant's integrated safety analysis (ISA) summary. The following subsections identify the areas of review for each of these components. Greater detail on each component is provided in Section 9.4, which specifies the review acceptance criteria.

9.3.1 Environmental Report

The regulatory requirements for the environmental report are contained in 10 CFR Part 51. These regulations were promulgated by the Commission to implement the National Environmental Policy Act (NEPA) of 1969, which requires an assessment of the environmental impacts for all major Federal actions. The NRC staff conducts an independent assessment for all licensing actions that may have a significant effect on the environment, based on the information provided by the applicant in the environmental report. This assessment is documented in an EA or EIS. Actions listed in 10 CFR Part 51.22(c) have been determined by the Commission to have insignificant environmental impacts and are categorically excluded

from the requirement for an environmental assessment and an environmental report. However, the

applicant may be required to submit information to the NRC to justify the applicability of the categorical exclusion.

The areas of review for the environmental report correspond to the content specified in 10 CFR 51.45:

- Date of Application
- Environmental Considerations
  - Description of the proposed action
  - Purpose of the proposed action
  - Description of the affected environment
  - Discussion of considerations (including environmental impacts and alternatives to the proposed action)
- Analysis
- Status of Compliance
- Adverse Information

The environmental report may include or reference information submitted to the NRC for prior licensing actions.

9.3.2 Environmental Protection Measures

The regulatory requirements for environmental protection are contained in 10 CFR Parts 20, 51, and 70. The NRC staff environmental review is focused on that part of the applicant's plant-wide safety program that is established to control and assess the level of radioactive and nonradioactive releases (gaseous, liquid, and solid) to the environment. Therefore, aspects of the applicant's radiation protection program for effluent control, as well as effluent and environmental monitoring practices, are reviewed. In addition, the plant-wide safety program is reviewed to ensure that the management controls specified to ensure that these activities meet license objectives.

To receive authorization to possess a critical quantity of special nuclear material, as defined in 10 CFR 70.4, an applicant must also perform an ISA in accordance with 10 CFR 70.60(d)(1). Guidance on the ISA is covered in Section 3.0 of this Standard Review Plan. The environmental safety review of the ISA summary will include a review of the identified potential accident sequences that result in radiological and nonradiological releases to the environment, as well as the controls specified by the applicant to reduce the risk of these accidents.

Thus, environmental protection includes three main components: (1) the radiation protection program, (2) effluent and environmental monitoring, and (3) the ISA summary and other ISA documentation as needed. The areas of review include:

9.3.2.1 Radiation Protection

- ALARA goals for effluent control

- Procedures, engineering controls, and process controls to maintain public doses ALARA
- ALARA reviews and reports to management
- Waste minimization practices and for new operations, design plans for waste minimization

9.3.2.2 Effluent and Environmental Monitoring

- In-place filter testing procedures for air cleaning systems
- Known or expected concentrations of radionuclides in effluents
- Physical and chemical characteristics of radionuclides in discharges
- Discharge locations
- Environmental media to be monitored and the sample locations
- Sampling collection and analysis procedures, including the minimum detectable concentrations of radionuclides
- Action levels and actions to be taken when the levels are exceeded
- Permits, including air discharge and National Pollutant Discharge and Elimination System permits
- Leak detection systems for ponds, lagoons, and tanks
- Pathways analysis methods to estimate public doses
- Recording and reporting procedures
- Solid waste handling and disposal programs

9.3.2.3 Integrated Safety Analysis

- Accident sequences (and associated facility processes) which, if unmitigated, result in releases to the environment
- Likelihood and environmental consequences of these accident sequences
- Controls relied on to reduce the unmitigated risk from “high” risk to an acceptable level
- Availability and reliability of controls

9.4 ACCEPTANCE CRITERIA

Acceptance criteria for the environmental report and for the environmental protection measures are described in Sections 9.4.1 and 9.4.2, respectively.

9.4.1 Environmental Report (or Categorical Exclusion Information)

The acceptance criteria for the environmental report are discussed in Section 9.4.1.1. For licensing actions which meet the requirements for a categorical exclusion as defined in 10 CFR 51.22(c), an environmental report is not required. However, if the action involves an amendment to licenses for fuel cycle plants, radioactive waste disposal sites, and other materials licenses identified in 10 CFR 51.60(b)(1) that involve changes in process operations or equipment, the applicant must justify that the action will not result in significant effects on the environment. The acceptance criteria for this demonstration are given in Section 9.4.1.2.

9.4.1.1 Environmental Report

A. Date of Application

The date of an application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, or for the conduct of any other activity, which the NRC has determined pursuant to 10 CFR 51 Subpart A will significantly affect the quality of the environment, is acceptable if the application is submitted at least 9 months before the commencement of construction, as required by 10 CFR Part 70.21(f).

B. Environmental Considerations

An adequate environmental report addresses the requirements of 10 CFR 51.45(b), as described below.

1. Description of the proposed action

The summary of the proposed action includes a brief description of the significant characteristics of the proposed facility, including the major site features and the major plant design and operating parameters. The description includes a complete discussion about how special nuclear material will be processed at the facility. If future construction is proposed, the description includes a proposed project schedule showing the dates for initiation of site preparation, plant construction, and operation.

2. Purpose of the proposed action

The statement of purpose demonstrates a need for the proposed project. This demonstration provides at least the following information: (a) the quantities of special nuclear material used for domestic benefit, (b) a projection of national and foreign requirements for the services, and (c) alternative sources of supply for the proposed facility's services. If delay of the proposed project would have effects on the nation's energy program or on the applicant's business (such as loss of contracts, jobs, or future business), these effects are discussed.

3. Description of the affected environment

The description of the affected environment includes:

a. Site location (including longitude and latitude) and facility layout
b. Regional demography and land use
c. Socioeconomic information**,** including low-income and minority populations within a 50 mile radius
d. Regional historic, archaeological, architectural, scenic, cultural, and natural landmarks
e. Local meteorology and air quality
f. Local surface water and groundwater hydrology
g. Regional geology and seismology

h. Local terrestrial and aquatic ecology

To the extent possible, this information reflects observations and measurements made over a period of years, especially for conditions that are expected to vary seasonally (e.g., precipitations, wind speed and direction, and groundwater levels).

4. Discussion of considerations

The discussion of considerations includes (a) the impact of the proposed action on the environment, (b) the adverse environmental effects of the proposed action and alternatives to the proposed action, (c) the relationship between short-term uses and long-term productivity, and (d) irreversible or irretrievable commitments of resources. The discussion of these points is acceptable if it includes the following considerations:

a. Impact of the proposed action on the environment

- Effects of site preparation and construction on land use and water use
- Effects of plant operation on the human population (including consideration of occupational and public radiation exposure) and important biota
- Any irreversible commitments of resources because of site preparation and plant construction and operation, such as destruction of wildlife habitat, removal of land from agricultural use, and diversion of electrical power
- Plans and policies regarding decommissioning and dismantling at the end of the plant's useful life
- Environmental effects of the transportation of radioactive materials to and from the site
- Environmental effects of accidents
- Impacts on air and water quality
- Impacts on cultural and historic resources

This section of the environmental report discusses the impacts on the environment in proportion to their significance. In addition, accident analyses provided in the report are consistent with the applicant's ISA.

b. Adverse environmental effects

The information submitted describes any adverse environmental effects that cannot be avoided should the proposal be implemented. This description is presented in quantitative terms to the maximum extent possible. This discussion makes clear which of these effects are unavoidable and subject to later amelioration and which are unavoidable and irreversible. The description includes specific measures that the applicant could take or plan to take to mitigate adverse effects.

c. Alternatives to the proposed action

The discussion of alternatives to the proposed action is sufficiently complete to aid NRC in developing and exploring, pursuant to Section 102(2)(E) of NEPA, "appropriate alternatives to recommended courses of action in any proposal which

involves unresolved conflicts concerning alternative uses of available resources." To the extent practicable, the environmental impacts of the proposal and the alternatives are presented in comparative form.

The discussion of alternatives includes siting alternatives and design alternatives. Comparable levels of information on each site need not be presented as long as the applicant presents sufficient information to facilitate a fair and reasonable comparison. The following factors are considered when comparing alternative sites:

- Physical characteristics of the area, including demographic, geological, hydrological, meteorological, and seismological conditions of the site and surrounding area
- Location of power sources and transmission lines
- Location of the major product market
- Location of raw materials, components, and sources of supply
- Availability of air, rail, roads, and water for transport of raw materials and supplies, finished products, and solid wastes
- Commitment of natural resources for site preparation and plant construction, including but not limited to the destruction or diminution of wildlife habitats, flora, woodlands, and marshlands
- Commitment of capital for site preparation and plant construction
- Cost of operation, including consideration of labor supply, prevailing wage rates, and other recurring or nonrecurring costs
- Availability of municipal services and facilities or, conversely, the cost of providing services such as water and sewage treatment
- Requirements for relocating homes and families
- Existing and projected land use and economic status of the community (e.g., urban, industrial, stable)

d. Relationship between short-term uses and long-term productivity

The relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity is discussed. Short-term uses are considered to be those that occur during the active life of the facility. Long-term productivity represents the use of the environment beyond decommissioning of the facility.

e. Irreversible or irretrievable commitments of resources

Any irreversible environmental commitments and irretrievable material resources that would be involved in the proposed action are discussed.

C. Analysis of Environmental Effects of Proposed Action and Alternatives

An adequate environmental report analyzes the environmental effects of the proposed action and alternatives. In accordance with 10 CFR 51.45(c), the analysis considers and balances the environmental effects of the proposed action and the alternatives available

for reducing or avoiding adverse environmental effects, as well as the environmental, economic, social, and other benefits of the proposed action.

This analysis quantifies, to the fullest extent practicable, the various factors considered. If the application involves renewal or amendment of a current license, environmental impacts are quantified using environmental monitoring data collected by the licensee. To the extent that there are important qualitative considerations or factors that cannot be quantified, the analysis discusses those considerations and factors in qualitative terms. The analysis contains sufficient data to aid the staff in its development of an independent analysis.

D. Status of Compliance

As required by 10 CFR 51.45(d), the applicant should list all Federal permits, licenses, approvals, and other entitlements, which must be obtained in connection with the proposed action. The list is acceptable if it is complete and current as of the application date.

In addition, 10 CFR 51.45(d) requires that the environmental report include a discussion of the status of compliance with applicable environmental quality standards and requirements including, but not limited to, applicable zoning and land-use regulations, and thermal and other water pollution limitations or requirements which have been imposed by Federal, State, regional, and local agencies having responsibility for environmental protection. The discussion is acceptable if it includes a discussion of whether each alternative will comply with such applicable environmental quality standards and requirements. The discussion include's, but is not limited to, the following federal laws:

- The National Historic Preservation Act of 1966
- The Fish and Wildlife Coordination Act of 1966
- The Wild and Scenic Rivers Act of 1968
- The Endangered Species Act Amendments of 1978
- The Coastal Zone Management and Improvement Act of 1990

E. Adverse Information

In accordance with 10 CFR 51.45(e), the preceding discussions and analyses are acceptable if they include information that is adverse to the proposed actions as well as information supporting the proposed action.

9.4.1.2 Categorical Exclusion

An environmental report is not required for actions identified in 10 CFR 51.60(b)(1) that involve an amendment to licenses for fuel cycle plants, radioactive waste disposal sites, and other materials licenses, which are not expected to result in significant environmental impacts. However, since these amendments involve changes in process operations or equipment, the applicant needs to justify that the changes will not result in significant environmental effects.

The information provided by the applicant to justify the categorical exclusion determination is acceptable if it demonstrates the following as specified in 10 CFR 51.22(c)(11):

- There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite
- There is no significant increase in individual or cumulative occupational radiation exposure
- There is no significant construction impact
- There is no significant increase in the potential for or consequences from radiological accidents

9.4.2 Environmental Protection

An applicant's proposed actions for environmental protection are acceptable if they provide for qualified and trained staff, effluent control, and effluent and environmental monitoring in accordance with NRC requirements. Using the acceptance criteria provided in Chapter 11 of this Standard Review Plan, the NRC staff will review the training and qualifications for plant personnel associated with environmental protection as described in the license application. This will include the training and qualification of managers, supervisors, technical staff, operators, technicians, maintenance personnel whose level of knowledge is important to maintain protection of public health and the environment. Managers and staff will be expected to have levels of education and experience commensurate with the responsibilities of their positions.

The acceptance criteria for the radiation protection program, and effluent and environmental monitoring, are given in Sections 9.4.2.1, 9.4.2.2, and 9.4.2.3, respectively.

9.4.2.1 Radiation Protection

In accordance with 10 CFR 20 Subpart B, each licensee must implement a radiation protection program, which is discussed in detail in Chapter 4 of this Standard Review Plan. The environmental review of the radiation protection program focuses on the applicant's methods to maintain public doses ALARA in accordance with 10 CFR 20.1101. NRC guidance on compliance with these regulations can be found in Regulatory Guide 8.37, "ALARA Levels for Effluents from Materials Facilities," July 1993.

Specifically, 10 CFR 20.1101(d) requires the applicant to establish a constraint on air emissions of radioactive material to the environment, excluding Radon-222 and its decay products, such that the individual member of the public likely to receive the highest dose will not be expected to receive a TEDE in excess of 10 mrem (0.1 mSv) per year from these emissions. The applicant must have procedures to report when this dose constraint is exceeded to the NRC in accordance with 10 CFR 20.2203 and take prompt appropriate corrective action to ensure against recurrence. NRC guidance on compliance with this regulation can be found in Regulatory Guide 4.20, "Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees Other Than Power Reactors," December 1996.

The environmental review of the radiation protection program also focuses on the applicant's waste minimization practices. Applicant's for new licenses are required to comply with 10 CFR 20.1406, which states that the applicant must describe how facility design procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste. Applicant's requesting amendment or renewal of existing licenses must minimize and control waste generation during operations as part of the radiation protection program in accordance with 10 CFR 20.1101 [62 FR 39082].

Guidance for waste minimization programs can be found in NRC Information Notice No. 94-23: "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994. More information on compliance with the decommissioning aspects of the waste minimization regulations can be found in Chapter 10.0 of this Standard Review Plan.

The proposed radiation protection program is acceptable if it satisfies the following criteria:

1. ALARA Goals for Effluent Control

   ALARA goals are set at a modest fraction (10% to 20%) of the values in Appendix B, Table 2, Columns 1 and 2 and Table 3 and the external exposure limit in 20.1302(b)(2)(ii), or the dose limit for members of the public, if the applicant proposes to demonstrate compliance with 10 CFR 20.1301 through a calculation of the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose.

   An applicant's constraint approach is acceptable if it is consistent with guidance found in Regulatory Guide 4.20 and the applicant's description of the constraint approach provides sufficient detail to demonstrate specific application of the guidance to proposed operations.

2. Procedures, Engineering Controls, and Process Controls

   The applicant uses procedures, engineering controls, and process controls to achieve ALARA goals for effluent minimization. Common control practices include filtration, encapsulation, adsorption, containment, recycling, leakage reduction, and the storage of materials for radioactive decay. Practices for large, diffuse sources such as contaminated soils or surfaces include covers, wetting during operations, and the application of stabilizers. The applicant demonstrates a commitment to reducing unnecessary exposure to members of the public and releases to the environment.

   Engineering options which do not result in a substantial reduction in collective dose and require unreasonable costs are not required. Reasonableness can be based on a qualitative or quantitative cost/benefit analysis. Quantitative analyses may use a $2000 per person-cSv (man-rem) value, as discussed in NUREG-1530, "Reassessment of the NRC's Dollar per Person-Rem Conversion Factor Policy."

3. ALARA Reviews and Reports to Management

   The applicant commits to annual review of the content and implementation of the radiation protection program, which includes the ALARA effluent control program. This review includes analysis of trends in release concentrations, environmental monitoring data, and radionuclide usage, determines whether operational changes are needed to achieve the ALARA effluent goals, and evaluates all designs for system installations or modifications. The applicant also includes a commitment to report the results to senior

   management along with recommendations for changes in facilities or procedures that are necessary to achieve ALARA goals.

4. Waste minimization

   Applications for new licenses are acceptable if they contain a description of how facility design procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, and minimize, to the extent practicable, the generation of radioactive waste. Waste minimizations programs proposed by applicants for both new and existing licenses are acceptable if the programs include:

   - top management support
   - methods to characterize waste generation, including types and amounts, and waste management costs, including costs of regulatory compliance, paperwork, transportation, treatment, storage, disposal, etc.
   - periodic waste minimization assessments to identify waste minimization opportunities and solicit employee or external recommendations
   - provisions for technology transfer to seek and exchange technical information on waste minimization
   - methods for implementation and evaluation of waste minimization recommendations

9.4.2.2 Effluent and Environmental Controls and Monitoring

The following regulations require effluent control and effluent and environmental monitoring measures for applicants requesting use of special nuclear material:

10 CFR Part 20

The applicant must establish effluent control and treatment measures in order to meet the dose limits and dose constraints for members of the public specified in 10 CFR Part 20, Subparts D and F. The applicant must also comply with the survey requirements of 10 CFR 20 Subpart F, the waste disposal requirements of Subpart K, the records requirements of Subpart L, and the reporting requirements of Subpart M.

10 CFR Part 51

The applicant must establish effluent and environmental monitoring systems to provide the information required by 10 CFR 51.60(a). 10 CFR 51.60(a) states that the environmental report or supplement to the environmental report submitted to support renewal or amendment of a license must include documentation of significant environmental changes, including changes resulting from operational experience or a change in operations.

10 CFR Part 70

In accordance with 10 CFR 70.22(a)(7) and 70.23(a)(3), the applicant must demonstrate that proposed facilities and equipment, including measuring and monitoring instruments and devices for the disposal of radioactive effluents and wastes, are adequate to protect public health and the environment. In addition, pursuant to 10 CFR 70.65(d), each application for a license to posses a critical mass of special nuclear material must contain a description of the environmental monitoring measures established by the applicant to assess the impact of licensed activities in accordance with 10 CFR Part 20.

Guidance documents on implementing these regulations includes the following publications:

- ANSI N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities"
- ANSI N42.18-1980, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents"
- NCRP Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996
- NRC Information Notice 94-07, “Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20,” January 28, 1994
- NRC Regulatory Guide 4.15, "Quality Assurance for Radiological Monitoring Programs (Normal Operations) ! Effluent Streams and the Environment"
- NRC Regulatory Guide 4.16, "Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants"

A. Effluent Control and Monitoring

The applicant’s effluent monitoring is acceptable if it meets the following criteria:

1. The known or expected concentrations of radioactive materials in airborne and liquid effluents are below the limits in 10 CFR Part 20, Appendix B, Table 2 or

below site specific limits established in accordance with 20.1302(c) and are ALARA.

2. All liquid and airborne effluent discharge locations are identified and monitored.

Airborne effluents from all operations associated with the plant, including areas not used for processing special nuclear material such as laboratories, experimental areas, storage areas, and fuel element assembly areas, are continuously sampled. For liquid effluents, representative samples are taken at each release point for the determination of concentrations and quantities of radionuclides released to an unrestricted area, including discharges to sewage systems. For continuous releases, samples are continuously collected at each release point. For batch releases, a representative sample of each batch is collected. If periodic sampling is used in lieu of continual sampling, the applicant shows that the samples are representative of actual releases.

Effluents are sampled unless the applicant has established, by periodic sampling or other means, that radioactivity in the effluent is insignificant and will remain so. In such cases, the effluent is sampled at least quarterly to confirm that effluents are not significant. Radionuclide analyses are performed more frequently than usual whenever a process change or other circumstance might cause a significant variation in the radionuclide composition. For the purposes of this Standard Review Plan, an effluent is significant if the concentration averaged over a calendar quarter is equal to 10% or more of the appropriate concentration listed in Table 2 of Appendix B to 10 CFR Part 20.

4. Radionuclide specific analyses are performed on selected composited samples unless (1) the gross alpha and gross beta activities are so low that individual radionuclides could not be present in concentrations greater than 10 percent of the concentrations specified in Table 2 or 3 of Appendix B to 10 CFR Part 20, or (2) the radionuclide composition of the sample is known through operational data, such as the composition of the feed material. Monitoring reports in which estimates of quantities of individual radionuclides are based on methods other than direct measurement include an explanation and justification of how the results were obtained.

Examples of cases in which operational data may not be adequate for the determination of radionuclide concentration are (1) plants processing uranium in which extraction, ammonium diuranate precipitation, ion exchange, or other separation processes could result in concentration of thorium isotopes (principally Th-234); (2) plants in which uranium of varying enrichments is processed; and (3) plants processing plutonium in which significant variation in the Pu-238/Pu-239 ratio among batches and the continuous in-growth of Am-241 would preclude the use of feed material data to determine the radionuclide composition of effluents.

Radionuclide analyses are performed more frequently than usual under three circumstances: (1) at the beginning of the monitoring program until a predictable radionuclide composition in effluents is established; (2) whenever there is a

significant unexplained increase in gross radioactivity in effluents; or (3) whenever a process change or other circumstance might cause a significant variation in the radionuclide composition.

5. The sample collection and analysis methods and frequencies are appropriate for the effluent medium and the radionuclide(s) being sampled. Sampling methods ensure that representative samples are obtained by use of appropriate sampling equipment and sample collection and storage procedures. Monitoring instruments are calibrated at least annually, or more frequently if suggested by the manufacturer.

6. The proposed action levels and actions to be taken if the levels are exceeded are appropriate. The action levels are incremental, such that each increasing action level results in a more aggressive action to assure and control effluents. A slightly higher than normal concentration of a radionuclide in effluent triggers an investigation into the cause of the increase. An action level is specified that will result in the shutdown of an operation if this level is exceeded. These action levels are selected based on the likelihood that a measured increase in concentration could indicate potential violation of the effluent limits.

7. The minimum detectable concentration (MDC) for sample analyses is not more than 5 percent of the concentration limits listed in Table 2 of Appendix B to 10 CFR Part 20. If the actual concentrations of radionuclides in samples are known to be higher than 5 percent of the 10 CFR Part 20 limits, the analysis methods need only be adequate to measure the actual concentration. However, in such cases, the MDC is low enough to accommodate fluctuations in the concentrations of the effluent and the uncertainty of the MDC.

8. The laboratory quality control procedures are adequate to support the validity of the analytical results. These QC procedures include the use of established standards such as those provided by the National Institute of Standards and Technology (NIST), as well as standard analytical procedures, such as those established by the National Environmental Laboratory Accreditation Conference.

9. The descriptions of applicable Federal and/or State standards for discharges and any permits issued by local, State, or Federal governments for gaseous and liquid effluents are complete and accurate.

10. If the applicant proposes to adjust the effluent concentrations in Appendix B to 10 CFR 20 in accordance with 20.1302(c) to take into account the actual physical and chemical characteristics of the effluents, the information related to aerosol size distributions, solubility, density, radioactive decay equilibrium, and chemical form is complete and accurate for the radioactive materials to justify the derivation and application of the alternative concentration limits.

11. The systems for the detection of leakage from ponds, lagoons, and tanks are adequate to detect and assure against any unplanned releases to groundwater, surface water, or soil.

12. Releases to sewer systems are controlled and maintained to meet the requirements of 10 CFR 20.2003, including (i) the material is water soluble; (ii) known or expected discharges meet the effluent limits of 10 CFR 20 Appendix B, Table 3; and (iii) the known or expected total quantity of radioactive material released into the sewer system in a year does not exceed 5 Ci (185 GBq) of ^{3}H, 1 Ci (37 GBq) of ^{14}C, and 1 Ci (37 GBq) of all other radioactive materials combined. Solubility is determined in accordance with the procedure described in NRC Information Notice 94-07.

13. Reporting procedures comply with the requirements of 10 CFR 70.59 and the guidance specified in Regulatory Guide 4.16. Reports of the concentrations of principal radionuclides released to unrestricted areas in liquid and gaseous effluents are provided and include the MDC for the analysis and the error for each data point.

14. If the licensee proposes to demonstrate compliance with 10 CFR 20.1301 through a calculation of the total effective dose equivalent (TEDE) to the individual likely to receive the highest dose in accordance with 20.1302(b)(1), calculation of the TEDE by pathways analyses uses appropriate models and codes and assumptions that accurately represent the facility, the site, and the surrounding area; assumptions are reasonable; input data is accurate; all applicable pathways are considered; and the results are interpreted correctly.

    NCRP Report No. 123, "Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground," January 1996, provides acceptable methods for calculating the dose from radioactive effluents. Computer codes are acceptable tools for pathways analysis if the applicant is able to demonstrate that the code has undergone validation and verification to demonstrate the validity of estimates developed using the code for established input sets. Dose conversion factors used in the pathways analyses are acceptable if they are based on the methodology described in ICRP 30, "Limits for Intakes of Radionuclides by Workers" as reflected in Federal Guidance Report 11.

15. The applicant's procedures and facilities for solid waste handling, storage and monitoring result in safe storage of the material and timely disposition.

B. Environmental Monitoring

The scope of the applicant's environmental monitoring is acceptable if it is commensurate with the scope of activities at the facility and the expected impacts of operations as identified in the environmental report and meets the following criteria:

1. Background and baseline concentrations of radionuclides in environmental media have been established through sampling and analysis.

2. Monitoring includes sampling and analyses for monitoring of air, surface water, groundwater, soil, sediments, and vegetation, as appropriate.

3. The description of monitoring identifies adequate and appropriate sampling locations and frequencies for each environmental medium, the frequency of sampling, and the analyses to be performed on each medium.

4. Monitoring procedures employ acceptable analytical methods and instrumentation to be used. The applicant commits to a program of instrument maintenance and calibration appropriate to the instrumentation, as well as participation in round-robin measurement comparisons if the applicant proposes use of its own analytical laboratory for analysis of environmental samples.

5. Appropriate action levels and actions to be taken if the levels are exceeded are specified for each environmental medium and radionuclide.

   Action levels are selected based upon a pathways analysis that demonstrates that below those concentrations, doses to the public will be below the limits in 10 CFR Part 20, Subpart B, and are ALARA. The action levels specify the concentrations at which an investigation would be performed and levels at which process operations would be shut down.

6. MDCs are specified for sample analyses, and are at least as low as those selected for effluent monitoring in air and water. MDCs for sediment, soil, and vegetation are selected based upon the action levels to ensure sampling and analytical methods are sensitive and reliable enough to support application of the action levels.

7. Data analysis methods and criteria to be used for evaluating and reporting the environmental sampling results are appropriate and will indicate when an action level is being approached in time to take corrective actions.

8. The description of the status of all licenses, permits, and other approvals of plant operations required by Federal, State and local authorities is complete and accurate.

9. Environmental monitoring is adequate to assess impacts to the environment from potential radioactive and nonradioactive releases as identified in the ISA.

9.4.2.3 Integrated Safety Analysis

In accordance with 10 CFR 70.60, applicant's requesting a critical mass of special nuclear material are required to perform an ISA. The applicant's treatment of environmental protection in the ISA is acceptable if it fulfills the following criteria:

- The ISA provides a complete list of accident sequences which result in radiological and nonradiological releases to the environment.

- The ISA provides a reasonable estimate for the likelihood and consequences of each accident sequence identified.

- Adequate controls are identified for each accident sequence of environmental significance. The controls (engineering or administrative) will prevent of mitigate potential accidents to an acceptable level.

- Adequate levels of assurance are afforded to the controls to ensure that items relied on for safety will satisfactorily perform their safety functions. This may be accomplished through configuration management, training, and maintenance activities.

- The ISA uses acceptable methods for estimating environmental effects from accident sequences.

9.5 REVIEW PROCEDURES

The staff will review the environmental report and the environmental protection measures to verify that each meets the acceptance criteria in Section 9.4. If the applicant has not provided sufficient information to make these determinations, then a request for additional information (RAI) should be made in coordination with the facility project manager. The format for an RAI is specified in Chapter 4 of the Licensing Branch and International Safeguards "Materials Licensing Procedures Manual." Additional review procedures are provided in Sections 9.5.1 - 9.5.3.

9.5.1 Environmental Report

Review of the environmental report or information presented to support a categorical exclusion includes review of occupational exposure information. This review should be coordinated with the radiation safety reviewer to assess the adequacy of the information provided by the applicant.

9.5.2 Environmental Protection

For renewal and amendment applications, review of environmental protection by the environmental specialist will include coordination with the fuel cycle facility inspector responsible for environmental protection. Any comments or concerns that the inspector identifies will be addressed and resolved, and the Safety Evaluation Report (SER) (described in Section 9.6.1) for the licensing action will contain a statement indicating if the inspection staff has any objections to approval of the proposed licensing action. In addition, the review of applications will include review of inspection reports and semi-annual effluent reports submitted in accordance with 10 CFR 70.59 to assure licensee performance in environmental protection.

As part of the environmental protection review, the environmental specialist will review the ISA summary and other ISA documents as needed. All accident sequences identified in the ISA that can have significant environmental consequences will be reviewed to determine that the

list of potential accidents is complete and properly identified. This review will be coordinated with the ISA reviewer.

Evaluation of the ISA summary requires coordination with other technical reviewers. The environmental review of the controls will be coordinated with the reviewers for the specific assurance functions, such as training and maintenance. These assurance functions are usually reviewed by the Project Manager for the facility.

Finally, review of the complete ISA findings and conclusions may require examination of detailed supporting documents that have not been submitted for the public record and are instead located at the facility. The reviewer should decide, as a result of these reviews, what supporting documents need to be forwarded to the NRC for inclusion in the public record of the application. As a general rule, material that directly supports a licensing decision of reasonable assurance of safety should be a matter of public record. Whether the material is placed in the public record or only available at the facility, the reviewer will clearly cite in the SER what materials were examined, and what descriptions and commitments were considered and relied upon or the basis for the staff's safety decision.

9.6 EVALUATION FINDINGS

Documentation of the evaluation findings for the environmental protection review is contained in two types of products. A Safety Evaluation Report (SER) documents the review of the environmental protection program and the ISA summary or related documents. The EA or EIS documents the staff's independent assessment of the environmental impacts of the proposed action.

9.6.1 Safety Evaluation Report

In the SER, the staff will document the findings of the adequacy of the application, will describe the bases for the findings, and will recommend additional license conditions in areas where the license application is not adequate. The documentation will include the bases for the conclusions, including a discussion of the areas of review and how the information demonstrates that the acceptance criteria have been met.

Often, environmental protection is reviewed and evaluated in conjunction with the environmental report, and the environmental protection function is summarized in the EA or EIS. However, the EA or EIS does not become part of the license. Issues identified during the review should be discussed briefly in the SER, and any recommended license conditions based on the analysis in the EA or EIS should be added to the license.

If an EA and EIS were prepared for the licensing action, the date the documents were issued should be reported in the environmental safety section of the SER. If the EA resulted in a FONSI, the FONSI's publication date in the Federal Register should be included in the SER. If an EIS is prepared, the SER would include the Federal Register publication date for the Record of Decision. When applicable, the SER also documents the determination that an action meets a categorical exclusion.

9.6.2 Environmental Assessment, Finding of No Significant Impact,

Environmental Impact Statement

Before taking a licensing action, including issuance, renewal, or amendment, the appropriate NRC Branch Chief will determine whether the proposed action qualifies for a categorical exclusion under 10 CFR 51.22 or whether an EA or EIS should be prepared:

- An EA will be prepared if the action meets the criteria in 10 CFR Part 51.21. On completion of the EA, the NRC determines whether to prepare an EIS or a FONSI.

- An EIS will be prepared if the action meets the criteria in 10 CFR Part 51.20. An EA is not necessary if it is determined that an EIS will be prepared.

- A categorical exclusion will suffice if the action meets the criteria for categorical exclusions as defined in 10 CFR Part 51.22(c). (An action that qualifies for a categorical exclusion is usually identified at the start of the licensing review, and an ER is not required.)

Requirements for the preparation of an EIS, EA, or FONSI are described in detail in 10 CFR Part 51. Documents prepared in accordance with NEPA will follow pertinent NMSS procedures, including consultation with states (Policy & Procedures Letter 1-48), evaluation of environmental justice (Policy & Procedures Letter 1-50), and Chapter 6 of the NRC Division of Fuel Cycle Safety and Safeguards, Fuel Cycle Licensing Branch Manual. Sections 9.6.2.1 and 9.6.2.2 contain an overview of the regulatory requirements for an EA, FONSI, EIS and Record of Decision specified in 10 CFR Part 51**.** However, this discussion is not intended to be all-inclusive.

9.6.2.1. Environmental Assessment (EA)

The staff will prepare an EA that identifies the proposed action and includes the following, in accordance with 10 CFR 51.30:

1. A brief discussion of:

   a. The need for the proposed action
   b. Alternatives to the proposed action as required by Section 102(2)(E) of NEPA
   c. The environmental impacts of the proposed action and alternatives, as appropriate
   d. As required by NMSS Policy and Procedures letter 1-50, April 21, 1995, disproportionately high and adverse human health or environmental effects on low income and minority populations

2. A list of agencies and persons consulted and identification of sources used. During preparation of an EA, the staff will consult with affected States on environmental issues and will document such contact in the EA. This documentation will include the following information identified in NMSS Policy and Procedures Letter 1-48, January 1995:

a. The name of each State, agency (including contacted individual's name), or person consulted
b. date of consultation(s)
c. purpose for the consultation
d. brief summary of the views or comments expressed by the consulted party and the staff's resolution
e. reference to publicly available documents containing additional information, if applicable

Much of the information used to prepare the EA is provided by the applicant in the environmental report. However, the staff will perform independent analyses of the environmental impacts of the proposed action and will discuss the conclusions of these analyses in the EA. The EA should focus on the impacts of the proposed action and should be no more than 15 pages, unless necessary to explain any complicated environmental issues associated with the proposed action.

On completion of the EA, the appropriate NRC Branch Chief will determine whether to prepare an EIS or a FONSI on the proposed action. As discussed in Section 9.6.2.2 and provided in 10 CFR 51.33, a determination to prepare a draft FONSI may be made. As provided in 10 CFR 51.25, an EA is not necessary if it is determined that an EIS will be prepared.

9.6.2.2. Finding of No Significant Impact (FONSI)

When the staff makes a final finding that there are no significant environmental impacts for the proposed action, a final FONSI will be published in the Federal Register. The Commission will not take the proposed action, including license issuance, renewal, or amendment, until after the FONSI has been published. Requirements for the preparation of a FONSI for materials licensing actions are contained in 10 CFR 51.32-51.35. A FONSI will include the following:

a. Identification of the proposed action
b. Statement that the Commission has determined not to prepare an EIS for the proposed action
c. Brief presentation of the reasons why the proposed action will not have a significant impact on the quality of the human environment
d. The EA or a summary of the EA
e. A note of any other related environmental documents
f. A statement that the finding and any related environmental documents are available for public inspection and where the documents may be inspected

NRC may make a determination to prepare and issue a draft FONSI for public review and comment before making a final determination whether to prepare an EIS or a final FONSI on the proposed action. A draft FONSI may be prepared if a FONSI appears warranted, but the proposed action is similar to one that normally requires an EIS or is without precedent.

The draft FONSI will be identified as a "draft" and will contain the information specified above for a final FONSI. The draft FONSI will be accompanied by or will include a request for comments on the proposed action and the draft findings within 30 days, or a longer period as may be specified in the notice of the draft findings. This draft FONSI will be published in the Federal Register, distributed as provided in 10 CFR 51.74(a), and made available in accordance with 10 CFR 51.123.

When a draft FONSI is issued, a final determination to prepare an EIS or final FONSI will not be made until the last day of the public comment period has expired.

9.6.2.3 Environmental Impact Statement (EIS)

When the appropriate NRC Branch Chief determines that an EIS will be prepared for the licensing action, a Notice of Intent to prepare an EIS will be published in the Federal Register in accordance with 10 CFR 51.27, and a scoping process will be conducted in accordance with 10 CFR 51.28 and 51.29. The scoping process may include a public scoping meeting.

A draft EIS is prepared as soon as practicable after publication of the Notice of Intent and completion of the scoping process. The general requirements, the requirements on content, and the requirements on supplements to a Draft EIS are found in 10 CFR 51.70-51.72. Public comments will be solicited on the draft in accordance with 10 CFR 51.73, and the draft will be distributed according to 10 CFR 51.74. After receipt and consideration of comments, the staff will prepare a Final EIS in accordance with 10 CFR 51.90 and 51.91, which will be distributed in accordance with 10 CFR 51.93.

The scoping process for the EIS will begin after the notice of intent is published. The purposes of the process are set forth in 10 CFR 51.29(a). At the conclusion of the scoping process, the staff will prepare a concise summary of the determinations and conclusions reached during the scoping process, including the significant issues identified, and will send a copy of the summary to each participant in the scoping process. This summary will be signed by an NRC staff director. At any time before issuance of the draft EIS, the staff may revise the determinations if substantial changes are made in the proposed action, or if significant new circumstances or information arises that bears on the proposed action or its impacts.

1. Draft Environmental Impact Statement

   General requirements for the preparation of a Draft EIS are contained in 10 CFR 51.70-51.74. The draft must include the following:

   a. An analysis of major points of view concerning the proposed action and alternatives including significant problems and objections raised by other Federal, State, and local agencies, by any affected Indian tribes, and other interested persons
   b. A Discussion of the status of compliance with all Federal, State, and local permits, licenses, approvals, and other entitlements obtained in implementing the proposed action
   c. An analysis which considers and weighs the environmental effects of the proposed action and alternatives

d. A preliminary recommendation by the NRC staff concerning the proposed action

2. Final Environmental Impact Statement

The format of the final EIS is set forth in Section 1(a) of Appendix A to 10 CFR Part 51, and the content is specified in 10 CFR 51.91. The final EIS must include any comments on the draft EIS or on any supplement to the draft, which may include modification of alternatives, development of new alternatives, and modification of analyses. All substantive comments received on the draft will be attached to the final EIS and any relevant responsible opposing view not adequately discussed in the draft will be presented. The final EIS will include:

a. A summary of the final EIS
b. A discussion of the purpose and need for the proposed action
c. A discussion of alternatives including the proposed action
d. A description of the affected environment
e. A discussion of the environmental consequences and mitigating actions
f. A list of preparers
g. Final recommendation on the action to be taken

9.6.2.4 Record of Decision

A Record of Decision (ROD) will be published after preparation of the final EIS and may be integrated into any other record prepared by the NRC in connection with the action. Requirements for the preparation of a ROD for materials licensing actions are contained in 10 CFR 51.102- 51.103. A ROD will include the following:

a. A statement of the decision
b. Identification of the alternatives considered
c. Identification of the environmentally preferable alternative
d. Discussion of the preferences among the alternatives, based on economic and technical considerations, the NRC's statutory mission, and any essential considerations of national policy, which were balanced by the NRC in making the decision
e. Statement of whether the NRC has taken all practical measures within its jurisdiction to avoid or minimize environmental harm, and if not, to explain why those measures were not adopted
f. Summary of any license conditions and monitoring programs adopted in connection with mitigation measures

9.7 REFERENCES

American National Standards Institute, N13.1-1982, "Guide to Sampling Airborne Radioactive Materials in Nuclear Facilities".

American National Standards Institute, N42.18-1980, "Specification and Performance of On-site Instrumentation for Continuously Monitoring Radioactive Effluents".

National Council on Radiation Protection and Measurements, NCRP Report No. 123 I & II, *"Screening Models for Releases of Radionuclides to Atmosphere, Surface Water, and Ground,"* January 1996.

NRC Information Notice No. 94-23: "Guidance to Hazardous, Radioactive and Mixed Waste Generators on the Elements of a Waste Minimization Program," March 25, 1994.

NRC Information Notice 94-07, "Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage Under the Revised 10 CFR Part 20," January 28, 1994.

U.S. Nuclear Regulatory Commission, NMSS/FCSS/Fuel Cycle Licensing Branch, Rev. 5, *"Materials Licensing Procedures Manual,"* September 1996.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.15, Rev. 2, *"Quality Assurance for Radiological Monitoring Programs (Normal Operations)!Effluent Streams and the Environment,"* February 1979.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.16, Rev. 2, *"Monitoring and Reporting Radioactivity in Releases of Radioactive Materials in Liquid and Gaseous Effluents from Nuclear Fuel Processing and Fabrication Plants and Uranium Hexafluoride Production Plants,"* December 1985.

U.S. Nuclear Regulatory Commission, Regulatory Guide 4.20, *"Constraint on Releases of Airborne Radioactive Materials to the Environment for Licensees other Than Power Reactors,"* December 1996.

U.S. Nuclear Regulatory Commission, Regulatory Guide 8.37, *"ALARA Levels for Effluents from Materials Facilities"*, July 1993.

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U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

10.0 DECOMMISSIONING

10.1 PURPOSE OF REVIEW

The purpose of the review of the applicant's plans for decommissioning is to ensure that these plans provide reasonable assurance that the applicant will be able to decommission the facility safely and in accordance with NRC requirements.

At the time of the initial license application, and upon license renewal, the applicant/licensee may be required to submit a decommissioning funding plan (DFP). The purpose of NRC review of the DFP is to determine that the applicant/licensee has considered decommissioning actions which may be needed in the future, has performed a credible site-specific cost estimate for those actions, and has presented NRC with financial assurance to cover the cost of these actions in the future. The DFP, therefore, should contain an overview of the proposed decommissioning actions, the methods used to determine the cost estimate and the financial assurance mechanism. These must be in sufficient detail to allow the reviewer to determine that the decommissioning cost used in the DFP is reasonably accurate.

In general, decommissioning plans (DP) are submitted through license amendments prior to the initiation of decommissioning activities, for the entire site or some portion of the site. The review for a DP is more rigorous than the review of the DFP. A DP must contain a detailed description of the specific decommissioning activities to be performed and must be sufficient to allow the reviewer to assess the appropriateness of the decommissioning activities, the potential impacts on health and safety of the public, workers, and the environment and the adequacy of the actions to protect health and safety and the environment. The reviewer must ascertain that the applicant understands decommissioning requirements and procedures, and commits to health and safety during decommissioning.

10.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Environmental Reviewer
Technical and financial specialists in the Division of Waste Management

Supporting: Fuel facility inspection staff

10.3 AREAS OF REVIEW

The reviewer will evaluate the applicant's decommissioning funding plan or decommissioning plan in accordance with "NMSS Decommissioning Program Standard Review Plan" currently under development in the Division of Waste Management.

10.4 ACCEPTANCE CRITERIA

10.4.1 Regulatory Requirements

Decommissioning planning, financial assurance for decommissioning, recordkeeping for decommissioning, and waste and contamination minimization are required by the following NRC regulations:

10 CFR 70.22(a)(9)	Decommissioning Funding Plan
10 CFR 70.25	Financial Assurance and Recordkeeping for Decommissioning
10 CFR 70.38	Expiration and Termination of Licenses and Decommissioning of Sites and Separate Buildings or Outdoor Areas
10 CFR 20.1401-1406 (Subpart E)	Radiological Criteria for License Termination

10.4.2 Regulatory Guidance

Relevant regulatory guidance for decommissioning in license applications and amendment requests is included in the "NMSS Decommissioning Program Standard Review Plan" currently under development.

10.5 REVIEW PROCEDURES

Upon acceptance of the application/amendment for review, the primary reviewer will review the application against NRC requirements and acceptance criteria identified in "NMSS Decommissioning Program SRP". This review will be supplemented as appropriate by detailed review of any contamination and waste minimization plans submitted by the applicant in response to 10 CFR 20.1406. The reviewer will also coordinate with the principal reviewers for environmental protection under SRP 9.0 to confirm review of a new applicant's descriptions of plans for waste minimization, as well as plans for existing licensees to minimize contamination and reduce exposures and effluents as part of radiation protection established under 10 CFR Part 20. The purpose of this coordination is to ensure that any issues that are relevant to the environmental review are properly conveyed to the lead reviewers for these sections for consideration and resolution. Similarly, any decommissioning issues that arise in the

environmental review that are most suited for review under SRP 10.0 are conveyed to the primary reviewer for consideration and resolution.

If the review identifies the need for the applicant to submit information that has not already been included in the application, the reviewer will document these additional information needs in a Request for Additional Information (RAI). The RAI will be transmitted to the applicant with a request for the information in a reasonable amount of time (e.g., 30 to 60 days). Failure of the applicant to provide the information by the requested date, or on an alternative schedule that is mutually agreeable, could be grounds to terminating or suspending the application review.

In accordance with the FCLB licensing manual, the lead reviewer will coordinate with the Division of Waste Management for appropriate technical assistance reviewing proposed decommissioning plans and financial assurance. The lead reviewer will coordinate the evaluation of the application with reviewers assigned by the Division of Waste Management and will incorporate, as appropriate, RIAs and review findings in licensing correspondence and safety reports related to decommissioning.

If the staff's review verifies that sufficient information has been provided in the application to satisfy the acceptance criteria and requirements identified in SRP 10.4, the staff will document its review as follows:

> The NRC staff has reviewed the applicant/licensee's plans for financial assurance for decommissioning in accordance with SRP 10.0 Based upon this review, the NRC staff has determined that the applicant's plans for decommissioning and decommissioning financial assurance provide reasonable assurance of protection for members of the public and the environment and comply with NCR's regulations.

10.7 REFERENCES

Code of Federal Regulations, Title 10, Part 70, Domestic Licensing of Special Nuclear Material, U.S. Government Printing Office, Washington, DC.

Orlando, D. A., *et al*. 1997. *NMSS Handbook for Decommissioning Fuel Cycle and Materials Licensees*, U.S. Nuclear Regulatory Commission, NUREG/BR-0241.

U.S. Nuclear Regulatory Commission, date to de determined, *NMSS Decommissioning Program Standard Review Plan*, NUREG-XXX,

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

11.0 MANAGEMENT MEASURES

11.1 PURPOSE OF REVIEW

Management measures are functions that are performed by a licensee, generally on a continuing basis, that are applied to items relied on for safety, to ensure the items are available and reliable to perform their functions when needed. The phrase "available and reliable" as used in this rule means that, based upon the analyzed, credible conditions in the Integrated Safety Analysis (ISA), items relied on for safety will perform their intended safety function when needed to prevent an accident or mitigate the consequences of an accident. Management measures are implemented to ensure continuous compliance with the performance requirements, considering factors such as necessary maintenance, operating limits, common cause failures, and the likelihood and consequences of failure or degradation of the items and the measures. Management measures include configuration management, maintenance, training and qualifications, procedures, audits and assessments, and other quality assurance elements. The degree to which measures are applied to the items is a function of the item's importance in terms of meeting the performance requirements as evaluated in the ISA. In the Chapter 11 discussion that follows, quality assurance includes aspects of configuration management, maintenance, training and qualifications, procedures, and audits and assessments; however, these topic areas are discussed in greater depth in individual sections in this chapter because of their importance and because, in some cases, their applicability is broader in scope than what has been included under quality assurance.

The purpose of this review is to determine if the management measures applied to items relied on for safety, as documented in the ISA summary, provide reasonable assurance that the items will be available and reliable to perform their function when needed. The review should also determine whether the measures are applied to the items relied on for safety commensurate with their importance to safety (graded approach).

11.2 RESPONSIBILITY FOR REVIEW

Primary: Licensing Project Manager

Secondary: Quality Assurance: Quality Assurance Engineer
Configuration Management: Primary ISA Reviewer, Quality Assurance and Records Management Reviewers
Maintenance: Criticality, Chemical, Fire, Radiation Protection and Environmental Reviewers
Training and Qualification: Training Specialist, Quality Assurance, or Human Factors Reviewers

Procedures: Radiation Protection, Criticality and Fire Protection Engineers, Fuel Cycle Facility Inspector
Audits and Assessments: Quality Assurance Reviewer
Incident Investigations: None
Records Management: Quality Assurance Engineer

Supporting: Technical Discipline Engineers, Fuel Cycle Facility Inspectors, Resident Inspectors

11.3 AREAS OF REVIEW

11.3.1 Quality Assurance

The application must address the 10 CFR Part 70 requirements with respect to management measures, to include quality assurance elements. 10 CFR 70.62(d) requires that each applicant or licensee shall establish management measures to provide continuing assurance of compliance with the performance requirements of 10 CFR 70.61.

The reviewer should determine that a complete description of the applicant's application of QA elements to items relied on for safety is included in the application and should examine it in terms of the Acceptance Criteria of this section. The review objective is to obtain reasonable assurance of the implementation of accepted QA principles in the design, construction, operation, maintenance, and modification phases of a facility's life. Fundamental to this effort is the applicant's application of QA to the identified items relied on for safety resulting from the ISA and identified in the ISA summary. QA would also be applicable to the hazards analysis process in the applicant's ISA.

The application defines the levels of QA to be applied to items relied on for safety identified by the ISA (SRP Section 3.0). Further, the relationship between QA and other management measures should be described. The application assigns QA levels to each item relied on for safety. The applicant addresses its approach to determining the relative risk, or relative safety importance, of the various items relied on for safety to be treated by both maintenance and QA. This safety importance ranking will determine the levels of QA to be applied to individual items relied on for safety.

The reviewer should recognize that facility safety may not be the only criterion for QA at a fuel cycle facility. The applicant's customers and the NRC, under 10 CFR Part 50, may impose product-related QA criteria. The focus of the review of QA measures per this SRP is limited to ensuring the safety (nuclear safety, chemical safety, fire safety, etc.) of workers and the public, and protecting the environment (i.e., in relation to the performance requirements of 10 CFR 70.61). The review should ensure that the QA function is adequately coordinated and integrated with other management measures.

Since many QA elements may be described in other sections of the application, the reviewer should determine the applicant's commitment to overall QA, the selection of quality criteria and quality level, and the proposed method for implementation. The applicant may reference other areas of the application that present information relevant to QA. The reviewer should focus on the management controls applied to criticality, containment of licensed materials, personnel

protection, and environmental safety. With the application of graded QA, quality levels commensurate with the risk involved should parallel the same risk levels established for maintenance.

11.3.2 Configuration Management

This review should ensure that the applicant has a plan for or has implemented an acceptable configuration management (CM) function. Configuration management means ensuring, as part of the safety program, oversight and control of design information, safety information, and modifications (both temporary and permanent) that might impact the ability of items relied on for safety to perform their function when needed. The reviewer should determine, with reasonable assurance, that the applicant has described and committed to a CM function that assures consistency among the facility design and operational requirements, the physical configuration, and the facility documentation. The reviewer should also determine that the applicant's CM function captures formal documentation governing the design and continued modification of those facility structures, systems, and components (SSCs) and supporting management measures, as identified and described in the ISA. The review should assure that the CM function is adequately coordinated and integrated with the other management measures.

The NRC staff should review the applicant's descriptions and commitments for CM, focusing on the processes for documenting an established baseline configuration and controlling changes to it to preclude inadvertent degradation of safety. The reviewers should examine descriptions of the organizational structure responsible for CM activities and the process, procedures, and documentation required by the applicant for modifying the site; items relied on for safety and the supporting management measures. The staff review should focus on the applicant's management measures that ensure the disciplined documentation of engineering, installation, and operation of modifications; the training and qualification of affected staff; revision and distribution of operating, test, calibration, surveillance, and maintenance procedures and drawings; post-modification testing; and readiness review.

The NRC staff should review the following:

1. <u>CM Policy</u>

   The review should cover the applicant's description of overall CM functions, including at least the following topics: (a) the scope of the SSCs to be included in the CM function (b) objectives of each CM activity, (c) a description of each CM activity, and (d) the organizational structure and staffing interfaces.

   The review should examine the applicant's establishment of a baseline CM policy applicable to all operations, initially independent of the ISA. The review should also examine the applicant's proposed reduced level of CM that the applicant may propose for certain SSCs based on the ISA.

2. <u>Design Requirements</u>

The review should cover the applicant's demonstration that design requirements and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant's CM controls on the design requirements and the ISA should be evaluated.

3. Document Control

The review should include the applicant's methods used to establish and control documents within the CM function.

4. Change Control

The review should examine the applicant's commitments to ensure that the CM function maintains strict consistency among the design requirements, the physical configuration, and the facility documentation. An important component of this review is the applicant's process, within the CM function, for ensuring that the ISA will be systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety basis changes will be properly modified, authoritatively approved, and made available to personnel.

5. Assessments

The review should examine the applicant's commitments to conduct assessments, including initial and periodic examinations of the CM system, to determine the function's effectiveness, and to correct deficiencies, consistent with the acceptance criteria for "Audits and Assessments."

6. Design Reconstitution

The review should examine the applicant's discussion of design reconstitution of the current design basis that has been done for the purpose of the application, and how that reconstitution was/is translated into a fixed baseline design basis from which subsequent changes are measured.

11.3.3 Maintenance

The NRC staff will evaluate the applicant's description of its maintenance function. The applicant should demonstrate that items relied on for safety are inspected, calibrated, tested and maintained, to the level commensurate with the risk, to ensure their ability to perform their safety functions when called upon. These items relied on for safety are identified by the applicant in the ISA summary. The staff will review the applicant's description of how each of the following functions is implemented within the site organization. *Note that not every aspect of the four maintenance functions is necessarily required; the applicant is expected to identify the items relied on for safety in the ISA Summary and would justify assigning differing degrees*

of maintenance to item's relied on for safety based on the item's contribution to the reduction of risk.

1. Corrective maintenance

2. Preventive maintenance

3. Surveillance/monitoring

4. Functional testing

11.3.4 Training and Qualifications

Part 70 of Title 10 of the Code of Federal Regulations requires that personnel who perform activities relied on for safety be trained, tested, and retested as necessary to ensure that they understand, recognize the importance of, and are qualified to perform these activities in a manner that adequately protects (1) the health and safety of the public and workers and (2) the environment. As appropriate for their authority and responsibilities, these personnel should have the knowledge and skills necessary to design, construct, start-up, operate, maintain, modify, and decommission the facility in a safe manner. Therefore, the training, testing, retesting, and qualification of these personnel should be described in the application and should be reviewed by the staff. This should include the training, testing, retesting, and qualification of managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel, and other personnel who perform activities relied on for safety. The review of the training and qualification should address the following training objectives:

1. Organization and management of the training system
2. Trainee selection
3. Conduct of needs/job analysis and identification of tasks for training
4. Development of learning objectives as the basis for training
5. Organization of instruction using lesson plans and other training guides
6. Evaluation of trainee mastery of learning objectives
7. Conduct of on-the-job training
8. Systematic evaluation of training effectiveness
9. Personnel qualification
10. Applicant's provisions for continuing assurance

11.3.5 Procedures

The NRC staff should review the process the applicant has developed for the production, use and management control of written procedures. This should include the basic elements of identification, development, verification, review and comment resolution, approval, validation, issuance, change control, and periodic review. The review includes two general types of procedures:

1. Procedures used to directly control process operations, commonly called "operating procedures". These are procedures for workstation operators and should include directions for normal operations as well as off-normal events caused by human error or

failure of an item relied on for safety. Procedures of this type include required actions to ensure nuclear criticality safety, chemical safety, fire protection, emergency planning, and environmental protection; and,

2. Procedures used for activities that support the process operations, that are commonly referred to as "management control procedures". These are procedures used to manage the conduct of activities such as configuration management, radiation safety, maintenance, human-systems interface, quality assurance, training and qualification, audits and assessments, incident investigations, record-keeping and, reporting.

The NRC staff should review the following:

1. The method for identification of the procedures that are needed plant-wide. The ISA summary identifies items relied on for safety where human actions are important. Procedures should be provided for all necessary steps or operations that are conducted at the facility. Procedures should be provided for every element of management control that is discussed in the SRP sections.

2. Essential elements that are generic to all procedures including: criticality, chemical process and fire safety; warning notes; reminders or pertinent information regarding specific hazards or concerns which include station limits, MSDS availability, special precautions, radiation and explosive hazards; and, special personal protective equipment.

3. The method for creating and controlling procedures within plant management control systems. Includes how procedures are managed within the plant configuration management function.

4. Method for verifying and validating procedures before use. During procedure development, workers and operators review procedures to ensure they are usable and accurate.

5. The method and schedule for periodically reverifying and revalidating procedures.

6. The method for ensuring that current procedures are available to personnel and that personnel are qualified to use the latest procedures.

11.3.6 Audits and Assessments

The applicant should describe a system of audits and assessments which consists of two distinct levels of activities: an audit activity structured to monitor compliance with regulatory requirements and license commitments, and an assessment activity oriented to determining the effectiveness of the activities in achieving applicant-specified objectives that ensure continued availability and reliability of items relied on for safety.

The reviewer should examine the applicant's presentation with respect to:

1. The commitments to audit and assessment activities;

2. The use of qualified and independent audit and assessment personnel;

3. The general structure of typical audits and assessments;

4. The facility procedures to be used to direct and control the audit and assessment activities;

5. The planned use of the results of the audit and assessment activities;

6. The documentation to record and distribute the findings and recommendations of these audits and assessments; and

7. The planning and implementation of corrective actions based on the findings and recommendations.

11.3.7 Incident Investigations

The NRC staff should review the applicant's policy, procedures, and management structure for investigating abnormal events and completing appropriate corrective actions. The review should include the provisions for establishing investigating teams, the methods for determining root causes, and procedures for tracking and completing corrective actions and for documenting the process for the purpose of applying the "lessons learned" to other operations.

11.3.8 Records Management

The requirements for the management of records vary according to the nature of the facility and the hazards and risks posed by it. The staff should review areas related to the handling and storing of health and safety records and the records generated or needed in the design, construction, operation, and decommissioning phases of the facility. The staff should review the following:

1. The process whereby records, including training, dosimetry, effluents, classified information, facility structures, systems, or components relied on for safety, and failure logs are created, selected, verified, categorized, indexed, inventoried, protected, stored, maintained, distributed, deleted, or preserved. The review should ensure that the records management function is adequately coordinated and integrated with other management measures.

2. The handling and control of various kinds of records and the methods of recording media that comprise the records (including contaminated and classified records).

3. The physical characteristics of the records storage area(s) with respect to the preservation and protection of the records for their designated lifetimes.

11.4 ACCEPTANCE CRITERIA

11.4.1 Regulatory Requirements

The requirements for fuel cycle facility management measures, including QA elements, configuration management, maintenance, training and qualifications, procedures, audits and assessments, incident investigations, and records management are specified in 10 CFR Part 70, “Domestic Licensing of Special Nuclear Material," as revised (e.g., Part 70 definitions; 70.62(d)).

10 CFR 70.62(d), *Safety Program and Integrated Safety Assessment,* requires that the applicant’s management measures ensure that engineered and administrative controls and control systems that are identified as items relied on for safety pursuant to §70.61(e) are maintained to ensure they are available and reliable to perform their function when needed

The requirement specifically applicable to personnel training and qualification is Code of Federal Regulations, Title 10 (10 CFR), Part 19, “Notices, Instructions and Reports to Workers: Inspection and Investigations,” specifically Section 19.12, "Instructions to Workers."

The regulation requirement for procedures that protect health and minimize danger to life is specified in 10 CFR 70.22(a)(8).

The requirements specified in 10 CFR 70.65(b) require organization and management controls to provide reasonable assurance that management systems and structures are in place and effective in planning, implementing, performing audits and assessments, and controlling site operations in a fashion that ensures comprehensive management control and oversight function of the health, safety, and environment.

Incident investigation and reporting required by 10 CFR 70.74(a) and (b).

11.4.2 Regulatory Guidance

American National Standard Institute/American Society of Mechanical Engineers standard, ANSI/ASME NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications.”

ANSI/ISO/ASQ 9000 series quality management standards.

International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, “Establishing and Implementing a Quality Assurance Program;” DOE’s September 1997 draft “Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C.”

U.S. Nuclear Regulatory Commission, *Guidance on Management Controls/Quality Assurance, Requirements for Operation, Chemical Safety, and Fire Protection for Fuel Cycle Facilities*, Federal Register 54 (No. 53), 11590!11598, March 21, 1989.

NUREG-1220, “Training Review Criteria and Procedures,” Revision 1, January 1993.

11.4.3 Regulatory Acceptance Criteria

11.4.3.1 Quality Assurance

To be acceptable, the applicant's QA program should be structured to apply appropriate QA measures and controls to items relied on for safety, which may include site design features. QA measures may be applied in proportion to the importance of the item to the achievement of safety (graded approach). QA programs are expected to differ based on the purpose and complexity of the facility and processes to be controlled.

The ISA summary should identify the items relied on for safety, the degree of their importance to safety, and the related controls that are required for safety. An applicant may choose to apply the highest level of QA and control to all items relied on for safety or may grade its QA in proportion to the importance of the item to the achievement of safety.

When used, the graded approach for the application of QA should be described and should parallel the maintenance defined and applied by the applicant as described in the application. At a minimum, the same items relied on for safety that are included in the maintenance program should have appropriate QA controls. When the applicant implements a graded QA program, the relative risk importance ranking of items relied on for safety, as established within the maintenance program, should be the same as those used in QA. For each of the items relied on for safety as identified in the ISA summary, but commensurate with the feature's risk level, the applicant may identify and define the applicable level of QA. From that point on, the assignment of QA levels to be used may be based on the graded QA application.

A checklist for evaluating QA is given below. When QA is graded, the attributes listed below are applied collectively only for accident sequences that run the highest level of risk. QA requirements may be reduced by modifying or eliminating attributes based upon evaluations performed and documented in the ISA.

1. The applicant describes the a) organizational structure; b) functional responsibilities; and c) charts of the lines, interrelationships, and areas of responsibility and authority for all organizations performing activities relied on for safety including the organization of the applicant and, as applicable, its principal contractors (architect/engineer, constructor, construction manager, and operator). Persons or organizations responsible for ensuring that appropriate QA has been established and verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities.

2. The applicant commits to meet the applicable requirements of American National Standard Institute/American Society of Mechanical Engineers standard, ANSI/ASME NQA-1-1994, “Quality Assurance Requirements for Nuclear Facility Applications.” Alternatively, QA elements applied to items relied on for safety can be developed, and committed to, using one or more of the following documents: 1) ANSI/ASME NQA-1-1994; 2) an appropriate ISO 9000 quality management standard; 3) an appropriate ANSI/ISO/ASQ 9000 quality systems standard; 4) International Atomic Energy Agency 1995 Safety Guide 50-SG-Q1, “Establishing and Implementing a Quality Assurance Program;” 5) DOE’s September 1997 draft “Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C;” and/or 6) other documents that provide equivalent QA for such facilities. The commitment may describe the applicants graded approach to QA, describing controls implemented consistent with an item’s importance to safety, or the commitment may describe a QA program applied to all items

relied on for safety. The QA function is well-documented, planned, implemented, and maintained to ensure the availability and reliability of items important to safety. It should be functional prior to performing the ISA required by Part 70.

3. A design control system is established that includes design inputs, process, analyses, verification, interfaces, changes, and design documentation and records (see sections 11.3.2, 11.4.3.2, 11.5.2.2, 11.6.2 for details on configuration management).

4. Applicable design bases and other requirements necessary to ensure adequate quality are included or referenced in documents for procurement of items or services relied on for safety. To the extent necessary, suppliers are required to have QA consistent with the quality level of the item or service to be procured.

5. Activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate for the circumstances (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures).

6. The preparation, issuance, and changes of documents that specify quality requirements or prescribe activities affecting quality are controlled to ensure that the appropriate documents are in use. Document changes are reviewed for adequacy and approved for implementation by authorized personnel (see sections 11.3.2, 11.4.3.2, 11.5.2.2, 11.6.2 for details on configuration management and sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures).

7. Purchased items and services relied on for safety are controlled to ensure conformance with specified requirements.

8. Provisions are made to identify and control items relied on for safety and to ensure that incorrect or defective items are not used.

9. Controls are established to ensure the acceptability of special processes used in the course of construction, maintenance, modifications, and testing activities, such as welding, heat treating, nondestructive testing, and chemical cleaning and that they are performed by qualified personnel using qualified procedures and equipment.

10. Inspection required to verify conformance of items relied on for safety with requirements is planned and executed. Inspection requirements are specified in written procedures with provisions included for documenting and evaluating inspection results (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures). Personnel qualification programs are established for Inspection test personnel (see sections 11.3.4, 11.4.3.4, 11.5.4, 11.6.4 for details on training and qualifications).

11. Tests are conducted to verify that items relied on for safety conform to specified requirements and will perform satisfactorily in service. Test requirements are specified in written procedures with provisions included for documenting and evaluating test results (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures). Personnel qualification programs are established for test personnel (see sections 11.3.4, 11.4.3.4, 11.5.4, 11.6.4 for details on training and qualifications).

12. Provisions are made to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals to maintain performance within required limits.

13. Provisions are made to control the handling, storage, shipping, cleaning, and preservation of items relied on for safety in accordance with work and inspection instructions to prevent damage, loss, and deterioration caused by environmental conditions such as temperature or humidity.

14. Provisions are made to control the inspection, test, and operating status of items relied on for safety to prevent inadvertent use of nonconforming items or bypassing of inspections and tests.

15. Provisions are made to control the identification, segregation, disposition, and prevention of installation or use of nonconforming items relied on for safety.

16. Provisions are made to ensure that conditions adverse to safety are promptly identified and corrected and that measures are taken to preclude repetition. These actions should be documented and reported to appropriate levels of management (see sections 11.3.7, 11.4.3.7, 11.5.2.7, 11.6.7 for details on incident investigations and sections 11.3.6, 11.4.3.6, 11.5.2.6, 11.6.6 for details on audits and assessments).

17. Provisions are made for the identification, retention, retrieval, and maintenance of records that furnish evidence of the control of quality for items relied on for safety (see sections 11.3.8, 11.4.3.8, 11.5.2.8, 11.6.8 for details on records management).

18. Provisions are made for planning and scheduling assessments and audits to verify compliance with and to determine the effectiveness of QA; responsibilities and procedures are identified for assessing, auditing, documenting, and reviewing results and for designating management levels to review assessment and audit results; and provisions are made for incorporating the status of findings and recommendations in management reports (see sections 11.3.6, 11.4.3.6, 11.5.2.6, 11.6.6 for details on audits and assessments).

19. The applicant's provisions for continuing QA address reviews and updates of QA documents based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA program changes.

11.4.3.2 Configuration Management

The reviewers should determine that an applicant's CM function is acceptable if it satisfies the following criteria.

1. CM Policy

The applicant's description of overall CM functions describes at least the following topics: (a) the scope of the items relied on for safety (SSCs and management measures) to be included in the CM function (coordinate with the Section 3, ISA, reviewer for the application), (b) the objectives of each CM function activity, (c) a description of each CM function activity, and (d) the organizational structure and staffing interfaces. The functional interfaces with

maintenance, and training and qualification are of particular importance and should be addressed individually. The SSCs under CM should include all those items relied on for safety as defined by the ISA summary.

An important element of an applicant's overall CM policy is the establishment of a baseline CM policy applicable to all applicant operations, independent of ISA. That baseline initially includes all the CM functions described in this SRP Chapter. After an ISA is completed and SSCs are identified that may not be associated with high risk accident sequences, as defined by the ISA summary or the ISA, the applicant may choose to reduce or eliminate certain features of the CM function as applied to those lesser risk design or operational features. In that case, the applicant then, in its description of CM policy, defines the specific attributes of a reduced level or levels of CM that would be applied to selected items relied on for safety, and in the ISA identifies those items that will be assigned the lesser category of CM.

2. Design Requirements

The applicant demonstrates that design requirements and associated design bases have been established and are maintained by an appropriate organizational unit. The applicant demonstrates that the design requirements and the ISA are kept current and that suitable hazard/accident analysis methods, including controlled computer codes, if used, are available and are properly used to evaluate safety margins of proposed changes. Technical management review and approval procedures are described. The specific items relied on for safety included in the CM function are identified within the ISA summary report.

3. Document Control

The applicant describes an acceptable method to establish and control documents within the CM function, including cataloging the document data base, the information content of the document data base, maintenance and distribution of documents, document retention policies, and document retrieval policies. A list of the types of documents controlled is established and includes key documents, such as drawings, procurement specifications, engineering analyses, operating procedures, training/qualification records, and preventive and corrective maintenance procedures, and maintenance completion records.

4. Change Control

The applicant demonstrates that the CM function maintains strict consistency among the design requirements, the physical configuration, and the facility documentation. The applicant describes an acceptable process for identifying and authorizing proposed changes, performing appropriate technical and safety reviews of proposed changes, approving changes, implementing changes, and documenting changes. The applicant describes an acceptable process, within the CM function, for ensuring that the ISA is systematically reviewed and modified to reflect design or operational changes from an established safety basis, and that all documents outside the ISA that are affected by safety basis changes are properly modified, authoritatively approved, and made available to personnel.

5. Assessments

The applicant confirms that assessments, including initial and periodic examinations of the CM system, are conducted to determine the program's effectiveness and to correct deficiencies. The applicant indicates that such assessments are systematically planned and conducted in accordance with an overall facility audit and assessment function (see sections 11.3.6, 11.4.3.6, 11.5.2.6, 11.6.6 for details on audits and assessments) .

6. Design Reconstitution [Existing Facilities Only]

The applicant describes the design reconstitution that has been done for the purpose of the application. Because this information may duplicate the plant design bases information described elsewhere to support the ISA, this information may be included by reference to other parts of the application. The applicant has reconstituted the current design bases, supporting analyses, requirements, and documentation that support items important to safety. The reconstitution process, including walk-downs, is complete and verifies that the configuration is consistent with as-built facility documentation.

11.4.3.3 Maintenance

The reviewers should find the applicant's submittal acceptable if the application includes the following:

1. Surveillance / monitoring

For items relied on for safety identified in the ISA summary, the applicant describes the surveillance function and its commitment to the organization and conduct of surveillance at a specified frequency, to measure the degree to which engineered safety functions meet performance specifications. This activity is used in setting preventive maintenance frequencies and the determination of performance trends for items relied on for safety . Applicant describes how results from incident investigations, review of the failure log required by §10 CFR 70.62(a)(3), and identified root causes, are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Records showing the current surveillance schedule, performance criteria, and test results for all items relied on for safety are maintained by the applicant. For surveillance tests that can only be done while equipment is out of service, proper compensatory measures are prescribed for the continued normal operation of a process.

2. Corrective maintenance

Applicant provides the documented approach used to perform corrective actions or repairs on items that are relied on for safety. The maintenance function provides a planned, systematic, integrated, and controlled approach for the repair and replacement activities associated with identified failures to items relied on for safety. After conducting corrective maintenance and prior to returning an item relied on for safety to operational status, if necessary, a functional test is conducted to ensure that a safety control performs as designed and provides the safety action expected. Applicant describes how results from incident investigations and identified root causes

are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Contractors that work on or near items relied on for safety identified in the ISA summary receive the same level of training and follow the same work control activities as listed above.

3. Preventive maintenance

Applicant provides a description of the preventive maintenance (PM) function that demonstrates a commitment to conduct preplanned and scheduled periodic refurbishing, partial or complete overhaul, for the purpose of ensuring that unplanned outages of selected safety functions do not occur. This activity includes using the results of the surveillance component of maintenance and the failure log required by §70.62(a)(3). Instrumentation calibration and testing is addressed by the applicant as part of this component. The applicant describes how the function will be designed to ensure that the objective of preventing failures through maintenance is appropriately balanced against the objective of minimizing unavailability of safety features because of monitoring or preventive maintenance. After conducting PM and prior to returning a safety control to operational status, if necessary, a functional test is conducted to ensure that a safety control performs as designed and provides the safety action expected. The methodology or basis used to determine PM frequency is described. Applicant describes how results from incident investigations and identified root causes are used to modify the affected maintenance function and eliminate or minimize the root cause from recurring. Feedback from the PM and corrective maintenance function is used to change frequency or scope of the maintenance activity. A rationale for deviation from industry standards or vendor recommendations is provided. Records showing the PM schedule, and results, for all safety features subject to this maintenance component are maintained by the applicant.

4. Functional testing

Applicant includes a description of and commitment to the functional testing of items relied on for safety for surveillance purposes or if needed after corrective/ preventive maintenance or calibration. These tests are conducted using approved procedures and include compensatory measures while the test is being conducted. The description includes the methods used, the frequency, and the basis for each. Applicant ensures that the functional tests cover all aspects of the safety control. As an example, if a level controller is used to actuate a three-way valve and divert flow to an alternate tank, then the level monitor sending unit and the valve, power supplies, utility services, and any corresponding local or control room displays are tested at the same time during the functional test. The intent is to simulate actual upset conditions and demonstrate that the safety control is available and reliable and will function in the field as intended. Applying a milliamp signal across the leads of the level monitor and watching the valve cycle open or close, is not considered an adequate functional test. During startup of new process equipment these functional tests are conducted, documented and maintained for NRC review. Records showing the functional test schedule, and results, for all items relied on for safety subject to this maintenance component, and results, are maintained by the applicant.

If any Administrative Control is identified as being an item relied on for safety, the applicant should provide a discussion on how it is assured that this type of item relied on for safety (i.e., administrative control) is available and reliable to perform its intended safety function.

The work control methods listed below are applied to the corrective, preventive and functional testing maintenance elements and include (as applicable): a) authorized work instructions with detailed steps and a reminder on the importance of the items relied on for safety identified in the ISA summary; b) parts lists; c) as built or redlined drawings; d) a notification step to the operations function prior to conducting repairs and removing a safety control from service; e) work permits for welding and cutting, confined space or radiation related work; f) replacement with like/kind parts and the control of new or replacement parts to ensure compliance with 10 CFR Part 21; g) compensatory measures while performing work on items relied on for safety; h) procedural control of removal of components from service for maintenance and for return to service; i) ensuring safe operations during the removal of items relied on for safety from service; and j) notification to operations personnel that repairs have been completed. Written procedures for the performance of maintenance includes steps a) through j) (see sections 11.3.5, 11.4.3.5, 11.5.2.5, 11.6.5 for details on procedures). All work requests and maintenance procedures include technical and safety discipline reviews and approval, as well as approval by responsible management.

The four maintenance elements described above are covered by elements of the management measures discussed in SRP Section 11.0. The applicant includes a discussion or provides references, of how the maintenance function utilizes, interfaces with, or is linked to the various management measures. As an example, maintenance workers are trained and qualified to perform their duties and a description of the link between maintenance and the training and qualification function is described.

11.4.3.4 Training and Qualification

The NRC reviewers should find the applicant's submittal regarding personnel training and qualification provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied. In addition to the regulatory review criteria given below, SRP Subsections 4.1.5.4 and 4.1.5.6 provide specific criteria for training and qualification for radiation safety personnel. Thus, some of the information specified below may be found in other sections of the SRP and incorporated by reference.

1. Organization and Management of Training - The organization and management of training are acceptable if the design, construction, start-up, operation, maintenance, modification, and decommissioning of the facility are organized, staffed, and managed to facilitate planning, directing, evaluating, and controlling a systematic training process that fulfills job-related training needs. Formal training should be provided for each position or activity for which the required performance is relied on for safety. The application should state what training will be conducted and which personnel will be provided this training.

The following commitments should be in the application regarding organization and management of training:

1. Line management is responsible for the content and effective conduct of the training.
2. The job function, responsibility, authority, and accountability of personnel involved in managing, supervising, and implementing training is clearly defined.
3. Performance-based training is used as the primary management tool for analyzing, designing, developing, conducting, and evaluating training.
4. Procedures are documented and implemented to ensure that all phases of training are conducted reliably and consistently.
5. Training documents are linked to the configuration management system to ensure that design changes are accounted for in the training.
6. Exemptions from training are granted to trainees and incumbents only when justified, documented, and approved by management.
7. Both programmatic and individual training records are maintained. These records, support management information needs and provide required data on each individual's training, job performance, and fitness for intended duty.

2. Trainee Selection - Trainee selection is acceptable if minimum requirements for trainees are specified for candidates whose activities are relied on for safety or who perform actions that prevent/mitigate accident sequences described in the ISA summary. Trainees should meet entry-level criteria defined for the position including minimum educational, technical, experience, and physical fitness (if necessary) requirements.

3. Conduct of Needs/Job Analysis and Identification of Tasks for Training - The conduct of needs/job analysis and identification of tasks for training are acceptable if the tasks required for competent and safe job performance are identified, documented, and included in the training.

Design personnel, construction personnel, operations personnel, training staff, and other subject matter experts, as appropriate, should have conducted or should conduct a needs/job analysis to develop a valid task list for specific jobs. The jobs treated in this manner should include - as a minimum - those responsible for managing, supervising, performing, and verifying the activities specified in the ISA summary as preventing or mitigating accident sequences. Each task selected for training (initial or continuing) from the facility-specific task list should be matrixed to supporting procedures and training materials. The facility-specific list of tasks selected for training and the comparison to training materials should be reviewed on an established schedule and updated as necessitated by changes in procedures, facility systems/equipment, or job scope.

4. Development of Learning Objectives as the Basis for Training - The development of learning objectives as the basis for training is acceptable if learning objectives that identify training content and define satisfactory trainee performance are derived from job performance requirements. Learning objectives should state the knowledge, skills, and abilities the trainee should demonstrate; the conditions under which required actions will take place; and the standards of performance the trainee should achieve upon completion of the training activity. Learning objectives should be sequenced based on their relationship to each other.

5. Organization of Instruction Using Lesson Plans and Other Training Guides - The organization of instruction using lesson plans and other training guides is acceptable if the plans/guides are based on the required learning objectives derived from specific job

performance requirements. Plans/guides should be used for in-class training and on-the-job training and should include standards for evaluating proper trainee performance. Review and approval requirements should be established for all plans/guides and other training materials before their issue and use.

6. Evaluation of Trainee Mastery of Learning Objectives - The evaluation of trainee mastery of learning objectives is acceptable if trainees are evaluated periodically during training to determine their progress toward mastery of job performance requirements and at the completion of training to determine their mastery of job performance requirements.

7. Conduct of On-the-Job Training - The conduct of on-the-job training is acceptable if on-the-job training used for activities required by the ISA are fully described. On-the-job training should be conducted using well-organized and current performance-based training materials. On-the-job training should be conducted by designated personnel who are competent in the program standards and methods of conducting the training. Completion of on-the-job training should be by actual task performance. When the actual task cannot be performed and is therefore “walked-down,” the conditions of task performance, references, tools, and equipment should reflect the actual task to the extent possible.

8. Systematic Evaluation of Training Effectiveness - A systematic evaluation of training effectiveness and its relation to on-the-job performance is acceptable if it ensures that the training program conveys all required skills and knowledge and is used to revise the training, where necessary, based on the performance of trained personnel in the job setting. A comprehensive evaluation of individual training programs should be conducted periodically by qualified individuals to identify program strengths and weaknesses. Feedback from trainee performance during training and from former trainees and their supervisors should be used to evaluate and refine the training. Change actions (for example procedure changes, equipment changes, facility modifications) should be monitored and evaluated for their impact on the development or modification of initial and continuing training and should be incorporated in a timely manner. This should be accomplished through the configuration management system (see sections 11.3.2, 11.4.3.2, 11.5.2.2, 11.6.2 for details on configuration management). Improvements and changes to initial and continuing training should be systematically initiated, evaluated, tracked, and incorporated to correct training deficiencies and performance problems.

9. Personnel Qualification - The following commitments should be in the application regarding personnel qualification for managers, supervisors, designers, technical staff, construction personnel, plant operators, technicians, maintenance personnel and other staff required to meet NRC regulations:

1. Managers should have a minimum of a B.S./B.A. or equivalent. Each manager should have either management experience or technical experience in facilities similar to the facility identified in the application.

2. Supervisors should have at least the qualifications required of personnel being supervised with either one additional year experience supervising the technical area at a similar facility or should have completed the supervisor training.
3. Technical staff identified in the ISA summary whose actions or judgments are critical to satisfy the performance requirements identified in 10 CFR Part 70 (i.e. item relied

on for safety) should have a B.S. in the appropriate technical field and three years experience. Other technical staff should have a B.S. in the appropriate technical field and one year experience.

4. Construction personnel, plant operators, technicians, maintenance personnel, and other staff whose actions are required to comply with NRC regulations should have completed the applicant's training process or have equivalent experience or training.
5. Candidates for process operators should be required to meet minimum qualifications described in the application. Candidates for job functions other than process operators should also be required to meet minimum qualifications, but these minimum qualifications need not be described in the application.

10. Applicant's Provisions for Continuing Assurance - The applicant's provisions for continuing assurance of personnel training and qualification are acceptable if the submittal addresses periodic retesting of personnel as necessary to ensure that they continue to understand, recognize the importance of, and are qualified to perform their activities that are relied on for safety.

11.4.3.5 Procedures

The reviewer should determine that the applicant's process for developing and implementing procedures is acceptable if it satisfies the following:

1. Procedures are written or planned for the conduct of all operations involving controls identified in the ISA summary as items relied on for safety and for all management control systems supporting those controls.

2. Operating procedures contain the following elements: (a) purpose of the activity; (b) regulations, polices, and guidelines governing the procedure; (c) type of procedure; (d) steps for each operating process phase; (e) initial startup; (f) normal operations; (g) temporary operations; (h) emergency shutdown; (I) emergency operations; (j) normal shutdown; (k) startup following an emergency or extended downtime; (l) hazards and safety considerations; (m) operating limits (n) precautions necessary to prevent exposure of hazardous chemicals or licensed special nuclear material; (o) measures to be taken if contact or exposure occurs; (p) items relied on for safety associated with the process and their functions; (q) time frame for which the procedure is valid.

3. Management control procedures contain elements reflecting the important elements of the functions described in the applicable chapters of this SRP. Procedures exist to manage the following activities: a) design; b) configuration management; c) procurement; d) construction; e) radiation safety; f) maintenance; g) human-systems interface; h) quality assurance; i) training and qualification; j) audits and assessments; k) incident investigations; l) records management; m) criticality safety; n) fire safety; o) chemical process safety; and p) reporting requirements.

4. The applicant's method for identifying the procedures includes using ISA findings and conclusions to identify needed procedures. Process operating procedures provide specific direction regarding administrative controls to ensure process operational safety.

5. The applicant describes the method for identifying, developing, approving, implementing, and controlling operating procedures. This method includes, as a minimum, that (a) operating limits and controls are specified in the procedure; (b) procedures include required actions for off-normal conditions of operation as well as normal operations; (c) if needed, safety checkpoints are identified at appropriate steps in the procedure; (d) procedures are validated through field tests; (e) procedures are approved by management personnel responsible and accountable for the operation; (f) a mechanism is specified for revising and reissuing procedures in a controlled manner; (g) the quality assurance and configuration management programs at the plant ensure that current procedures are available and used at all work locations; and (h) the plant training program ensures that the required persons are trained in the use of the latest procedures available.

6. The applicant includes the following commitment regarding procedure adherence: "Activities involving licensed special nuclear material and/or items relied on for safety will be conducted in accordance approved procedures".

7. The applicant describes the types of procedures used during facility operation. These will typically include management control, operating, maintenance, and emergency procedures. The applicant provides information regarding the procedure categories used at the facility. The applicant develops procedures for site wide safe work practices to provide for the control of processes and operations with licensed special nuclear material and/or items relied on for safety and/or hazardous chemicals produced from licensed materials. These safe work practices apply to workers, visitors, contractors, and vendors. An acceptable identification discussion clearly states areas for which a procedure is required. Procedures are required for operator actions that are necessary to prevent or mitigate accidents identified in the ISA and ISA summary. The applicant provides a listing (in an appendix) of the types of activities that are covered by written procedures. The listing includes the topics of administrative procedures; system procedures that address startup, operation, and shutdown; abnormal operation/alarm response; maintenance activities that address system repair, calibration, inspection and testing; and emergency procedures. Appendix A provides an acceptable listing of the items to be included under each topic.

8. Applicant reviews procedures following unusual incidents, such as an accident, unexpected transient, significant operator error, or equipment malfunction, or following any modification to a system and revises procedures as needed.

9. Applicant ensures technical accuracy of procedures and that they can be performed as written. The discussion identifies who is responsible for verification. The verification process ensures that the technical information is included and correct, including formulas, set points, acceptance criteria and includes either a walk-down of the procedure in the field or a table-top walk through. The review process includes technical, cross-discipline reviews by affected organizations. This process includes both new procedures and procedure changes. The review ensures that the operating limits and controls identified in the ISA are specified in the procedures and that quality assurance requirements are identified and included in operating procedures. The applicant describes who can approve procedures and includes the approval level for each

procedure type. At a minimum, responsible management along with the safety disciplines approve new procedures and changes to existing procedures.

10. Documents are distributed in accordance with applicable distribution lists. A process is used to limit the use of outdated procedures. Copies are available to appropriate personnel. Issuance and distribution of procedures is documented and refers to the Records Management function.

11. The applicant has formal requirements governing temporary changes. Temporary changes do not involve a change to the ISA or involve an item relied on for safety. The review and approval process is documented. Temporary procedures may be issued only when permanent procedures do not exist to: a) direct operations during testing, maintenance, and modifications; b) provide guidance in unusual situations not within the scope of permanent procedures; and, c) ensure orderly and uniform operations for short periods when the plant, a system, or component of a system is performing in a manner not covered by existing permanent procedures, or has been modified or extended in such a manner that portions of existing procedures do not apply. The discussion includes establishment of a time frame for use of the temporary procedure and includes the same level of review and approval as that for permanent procedures.

12. Maintenance procedures involving items relied on for safety commit to the topics listed below for corrective, preventive, functional testing after maintenance, and surveillance maintenance activities:

    a. Pre-maintenance activity requires reviews of the work to be performed, including procedure reviews for accuracy and completeness.

    b. Steps that require notification of all affected parties (operators and supervisors) prior to performing work and upon completion of maintenance work. The discussion includes potential degradation of items relied on for safety during the planned maintenance.

    c. Control of work by comprehensive procedures to be followed by maintenance technicians. Maintenance procedures are reviewed by the various safety disciplines including criticality, fire, radiation, industrial, and chemical process safety. The procedures describe, as a minimum the following:

        i. Qualifications of personnel authorized to perform the maintenance or surveillance.

        ii. Controls on and specification of any replacement components or materials to be used (this should be controlled by the configuration management function to ensure like/kind replacement and adherence to 10 CFR Part 21.

        iii. Post-maintenance testing to verify operability of the equipment.

        iv. Tracking and records management of maintenance activities.

v. Safe work practices (e.g., lockout/tagout, confined space entry, moderation control or exclusion area, radiation or hot work permits, criticality, fire, chemical, environmental or human-systems interface issues).

13. Applicant conducts periodic reviews of procedures to ensure their continued accuracy and usefulness and establishes the time frame for reviews of the various types of procedures. At a minimum all operating procedures are reviewed every 5 years and emergency procedures are reviewed every year. The applicant describes the use and control of procedures. Provisions allow for operations to stop and place the process in a safe condition if a step of a procedure cannot be performed as written. Guidance identifies the manner in which procedures are to be implemented. Routine procedural actions that are frequently repeated might not require the procedure to be present. Procedures for complex jobs or dealing with numerous sequences where memory cannot be trusted may require valve alignment check sheets, approved operator aids or in-hand procedures that are referenced directly when the job is conducted.

11.4.3.6 Audits and Assessments

The NRC reviewers should find the applicant's submittal regarding audits and assessments provides reasonable assurance that the regulatory review criteria below are adequately addressed and satisfied.

1. Audits and Assessments - General: Audits and assessments are acceptable if:

   a. Internal audits, external audits and assessments are conducted by the applicant with a graded approach based on the results of the integrated safety analysis required by 10 CFR §70.62. Audits and assessments should objectively evaluate the effectiveness and proper implementation of QA for items relied on for safety and address the technical adequacy of the items being audited/assessed.

   b. The applicant describes, commits to, and justifies a frequency and scope of audits and assessments that address items relied on for safety. Audits and assessments should be performed in all areas where the requirements of QA are applicable. Audits and assessments should be regularly scheduled on the basis of the status and the safety significance of the items being audited/assessed and should be initiated early enough to ensure the implementation of effective QA.

   c. Policy directives are established for audits and assessments. For each activity to be audited/assessed, the policy directives cover schedules, guidance for conducting the audit or assessment, assigned responsibilities, and procedures for recording the results of the audit or assessment and ensuring that identified deficiencies are corrected in a timely and effective manner.

   d. The applicant identifies the position title, qualifications, and responsibilities of the manager responsible for the overall success of the audits and assessments. Other organizational responsibilities for audits and assessments may be identified by the applicant.

e. Training and qualification requirements for audit and assessment personnel are described. (SRP Section 11.4 addresses training and qualification requirements in detail.)

f. Each audit and assessment team has authority to investigate any aspect of the audited/assessed items and has access to all relevant information.

g. Performance indicators are established so that audits and assessments can determine the degree to which selected items relied on for safety are meeting the applicant's objectives to protect (1) the health and safety of the public and workers and (2) the environment.

h. Audits and assessments are conducted according to written procedures/ checklists.

i. Audits and assessments include detailed walk-downs of the area, including out-of-the-way and limited-access areas, with accurate, documented descriptions of deficiencies.

j. On-the-spot corrective actions are provided for, with appropriate documentation.

k. Audit and assessment results are reviewed with management having responsibility in the area audited/assessed.

l. Reports of findings and recommendations are documented and distributed to appropriate management for review and response. As described in SRP Section 11.3, a management corrective action program is administered to ensure timely and effective corrective action.

m. Audit and assessment deficiency data are analyzed and trended. Resultant reports, which indicate quality trends and the effectiveness of QA, are given to appropriate management for review, response, corrective action, and follow-up.

2. Audits: Audits are acceptable if, in addition to the acceptance criteria in 11.7.4.3.1 above,

a. Audit personnel have no direct responsibility for the items they audit.

b. Audits are led by appropriately qualified and certified audit personnel from the QA organization.

c. Audit team membership includes personnel (not necessarily from the QA organization) having technical expertise in the areas being audited.

d. Both technical and QA programmatic audits are performed to provide a comprehensive independent verification and evaluation of procedures and activities affecting the quality of items relied on for safety.]

e. Auditing organizations schedule and conduct appropriate follow-up to ensure timely and effective corrective action.

3. Internal Audits: Internal audits are acceptable if, in addition to the acceptance criteria in 11.7.4.3.2 above,

   a. Both technical and QA programmatic audits are performed to verify and evaluate the applicant's internal QA, procedures, and items.

   b. Audit reports are issued to appropriate management on a timely basis

   c. Reports on the status of audit-finding corrective actions are issued periodically to appropriate management

   d. During facility operation, internal audits address compliance with selected operating limits.

4. External Audits: External audits are acceptable if, in addition to the acceptance criteria in 11.7.4.3.2 above,

   a. Both technical and QA programmatic audits are performed to verify and evaluate suppliers' QA, procedures, and items.

   b. Audit reports are issued to appropriate internal and external management on a timely basis.

   c. Reports on the status of audit-finding corrective actions are issued periodically to appropriate internal and external management

5. Assessments: Assessments are acceptable if, in addition to the acceptance criteria in 11.7.4.3.1 above, responsible management personnel or qualified, but not necessarily certified, personnel (designated by responsible management) with no direct responsibility for the items being assessed perform the assessments.

6. Applicant's Provisions for Continuing Assurance: The applicant's provisions for continuing audits and assessments is acceptable if the submittal addresses reviews and updates of the description of its audits and assessments based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other changes that should be reflected in the description of its audits and assessments to keep it current.

11.4.3.7 Incident Investigations

The applicant's description and commitments in the application will be acceptable if the reviewer finds reasonable assurance of the following:

1. The applicant will establish teams to investigate abnormal events that may occur during operation of the facility, to determine the root cause(s) of the event, and to recommend corrective actions. These teams will be independent from the line function(s) involved

with the incident under investigation. Investigations will begin within 48 hours of the abnormal event, or sooner, depending on the safety significance of the event. The failure log required for items relied on for safety should be reviewed as part of the investigation.

2. The applicant will monitor and document corrective actions through completion.

3. The applicant will maintain documentation so that "lessons learned" may be applied to future operations of the facility. Details of the event sequence will be compared to accident sequences already considered in the ISA, and actions will be taken to ensure that the ISA includes the evaluation of the risk associated with accidents of the type actually experienced.

The applicant has a formal policy or procedure in place for conducting an incident investigation, and that policy or procedure contains the following elements:

1. A documented plan for investigating an abnormal event. This plan is separate from any required Emergency Plan. The investigation of an abnormal event should commence as soon as possible, commensurate with the safety of the investigative team, after the event has been brought under control.

2. A description of the functions, qualifications, and responsibilities of the management person who would lead the investigative team and those of the other team members, the scope of the team's authority and responsibilities, and assurance of cooperation of management.

3. Assurance of the team's authority to obtain all the information considered necessary and independence from responsibility for or to the functional area involved in the incident under investigation.

4. Procedures requiring maintenance of all documentation relating to abnormal events for 2 years or for the life of the operation, whichever is longer.

5. Guidance for the team conducting the investigation on how to apply a reasonable, systematic, structured approach to determine the root cause(s) of the problem. The level of investigation should be based on a graded approach relative to the severity of the incident.

6. Requirements to make available to NRC original reports of investigative teams, on request.

7. A system for monitoring to ensure completion of appropriate corrective measures.

The assessment of the adequacy of the applicant's commitments to establish and use a plan for the investigation of abnormal events will also be based upon the following acceptance criteria:

1. The licensee has described the overall plan and method for investigating abnormal events.

2. The functions, responsibilities, and scope of authority of investigating teams are documented in the plan.

3. Qualified internal or external investigators are appointed to serve on investigating teams. The teams will include at least one process expert and at least one team member will be trained in root cause analysis.

4. The applicant commits to prompt investigation of any abnormal events, and precursors to abnormal events (such as undetected failure of controls).

5. The investigation process and investigating team are independent of the line management and participants are assured of no retribution from participating in investigations.

6. A reasonable, systematic, structured approach is used to determine the root cause(s) of abnormal events.

7. Auditable records and documentation related to abnormal events, investigations, and root cause analysis are maintained. For each abnormal event, the incident report should include a description, contributing factors, root-cause analysis, and findings and recommendations. Relevant findings are reviewed with all affected personnel.

8. Documented corrective actions are taken within a reasonable period to resolve findings from abnormal event investigations.

11.4.3.8 Records Management

The reviewer will find the applicant's records management system for records acceptable if it satisfies the following criteria:

1. Records are specified, prepared, verified, characterized, and maintained.

2. Records are legible, identifiable, and retrievable for their designated lifetimes.

3. Records are protected against tampering, theft, loss, unauthorized access, damage, or deterioration for the time they are in storage.

4. Procedures are established and documented specifying the requirements and responsibilities for record selection, verification, protection, transmittal, distribution, retention, maintenance, and disposition.

5. The organization and procedures are in place to promptly detect and correct any deficiencies in the H&S records management system or its implementation.

Examples of records that should be included in the system are listed in Appendix B. Records are categorized by relative safety importance to identify record protection and storage needs and to designate the retention period for individual kinds of records. The procedures should:

a) assign responsibilities for records management; b) specify the authority needed for records retention or disposal; c) specify which records must have controlled access and provide the controls needed; d) provide for the protection of records from loss, damage, tampering, or theft or during an emergency; and e) specify procedures for ensuring that the records management system remains effective.

For computer codes/computerized data relied on for safety, the applicant establishes procedure(s) for maintaining readability and usability of older codes/data as computing technology changes. This could include transcribing the older forms of information (e.g., punched cards or paper tapes) and codes for older computing equipment to contemporary computing media and equipment.

11.5 REVIEW PROCEDURES

11.5.1 Acceptance Review

The primary reviewer should evaluate the application to determine whether it addresses the "Areas of Review" discussed in Section 11.3, above. If significant deficiencies are identified, the applicant should be requested to submit additional material before the start of the safety evaluation.

11.5.2 Safety Evaluation

After the primary reviewer determines that the application is acceptable for review in accordance with Section 11.5.1, above, the primary and secondary reviewers should perform a safety evaluation against the acceptance criteria described in Section 11.4. Review procedures for each criterion are discussed in the sections below.

11.5.2.1 Quality Assurance

After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the primary staff reviewer should confirm that the applicant (and the applicant's principal contractors') QA commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the QA input into the Safety Evaluation Report (SER). The secondary reviewer should review the QA information with respect to the acceptance criteria in Section 11.4. The secondary staff reviewer should determine whether the applicant has adequately planned the work to be accomplished and whether necessary policies, procedures, and instructions either are in place or will be in place before work starts. The review is based on an assessment of the material presented. It should provide reasonable assurance that the applicant's QA, maintenance, and configuration management are coordinated and that QA is an integral part of everyday work activities. The review should provide reasonable assurance that the applicant will be able to monitor the effectiveness of the implementation of QA and will make needed adjustments on a timely basis. The staff is to look for and measure the effectiveness of QA design, not just the existence of appropriate elements.

The secondary reviewer should also determine that the applicant has specified the QA criteria and the basis on which the criteria were selected and how they are apportioned within the

sections of the application as well as the proposed method for implementation. If the applicant references other sections of the application when describing its QA, the reviewer should review these other sections of the application to determine the applicant's commitment to QA and the proposed method for implementation.

The supporting reviewers should become familiar with the applicant's (and principal contractors') QA commitments and determine whether ongoing activities are in agreement with them.

Staff Reviewers of SRP Chapters 3 through 15 should determine whether items within their areas of review that are relied on for safety are specified to be within the appropriate level of the applicant's QA program.

On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP. The staff or applicant may also propose license conditions to ensure QA meets the acceptance criteria. The review should result in a determination that there is reasonable assurance that the applicant's (and the applicant's principal contractors') QA will provide reasonable assurance that items relied on for safety will perform their safety function in a satisfactory manner.

When the safety evaluation is complete, the secondary staff reviewer, with assistance from the other reviewers, should prepare the QA input for the SER as described in SER Section 11.6.1 using the acceptance criteria from SER Section 11.4.1.

11.5.2.2 Configuration Management

1. CM Policy Management

   The primary reviewer should consider whether the CM plan acceptably states management commitments, gives the policy directive, and defines key responsibilities, terminology, and equipment scope. The method for initiating immediate corrective actions should be reviewed. The secondary reviewers should examine the ISA summary and the ISA as needed for the identification of dependence on CM of items relied on for safety. Appropriate interfaces both within the CM function and with external organizations and functions should be examined. In particular, the functional interfaces with QA, maintenance, and training (including qualification) should be examined. The reviewers should look for the applicant's identification of required databases and the rules for their maintenance. The reviewers should examine implementing procedures for the CM function.

2. Design Requirements

   The primary reviewer should confirm that the design process leading to drawings and other statements of requirements proceeds logically from the design basis. The design basis is a set of facts, about the systems covered by CM, that has been reviewed and approved by appropriate authority within the organization. The reviewers should verify that specific personnel are assigned the responsibility for maintaining the design bases and requirements. These may be the same personnel that maintain the ISA and

controlled computer codes. The reviewers should verify that the items relied on for safety to be listed under CM are clearly defined in the requirements documents, along with the assignment of any grades or quality levels. The grades or quality levels, if specified, are based on the qualitative risk associated with postulated accident sequences in which the items relied on for safety are required to function. This part of the review should be coordinated with the ISA primary reviewer. The ISA summary specifies all items relied on for safety, and the applicant should have indicated in the ISA what level of CM attributes are applied to a particular item. However, in the ISA this indication may consist of only an index or category designation. The definition of the individual content of multiple CM levels, if used, should be in the CM Chapter of the application. The primary reviewer for the CM Chapter is responsible to determine if the reduced levels the applicant would apply to safety items for lesser risk accident sequences are adequate.

3. Document Control

The primary reviewer should evaluate the applicant's material showing that the CM system will capture documents that are relevant and important to safety. This includes design requirements, the ISA, as-built drawings, specifications, all safety-important operating procedures, procedures involving training, QA, maintenance, audits and assessments, emergency operating procedures, emergency response plans, system modification documents, assessment reports, and others, as necessary, that the applicant may deem part of the CM function. The primary reviewer should determine whether a controlled document database is used to control documents and track document change status. Rules of storage for originals or master copies of documents within the CM function follow the guidance of “Records Management.”

4. Change Control

The primary reviewer should ensure that the description of change control within the CM function commits to acceptable methods in place for: (a) the identification of changes in configurations relied on for safety; (b) technical and management review of changes, and (c) tracking and implementing changes, including placement of documentation in a document control center and dissemination to affected functions such as training, engineering, operations, maintenance, and QA. Post-modification testing of hardware (or procedure drills or walk-throughs) may be done in conjunction with periodic equipment performance monitoring and normal maintenance functions.

5. Assessments

The primary reviewer should ensure that both document assessments and physical assessments (system walkdowns) will be conducted periodically to check the adequacy of the CM function. The primary reviewer should ensure that all assessments and follow-ups are documented. These reports can provide a supporting basis for future changes. The primary reviewer should assure that assessments will include at least a sampling level of reviews of safety systems from design requirements through implementation.

7. Design Reconstitution [Existing Facilities Only]

Design reconstitution may be necessary for existing facilities if current design information is not adequate. The primary reviewer examines the applicant's description of work to establish, organize, and document design requirements and design bases for items for which design information was not available before the application was submitted. Of particular importance are the methods used to evaluate, verify, and validate reconstituted design data for SSCs. For existing facilities, the design requirements and physical configuration may have greatly changed according to the demands of a changed mission. If documentation has not kept pace, it will be necessary for the applicant to walk down systems, update drawings and specifications, perform new calculations and analyses, and otherwise rebuild the design bases. The reviewer looks for evidence that the applicant has considered system interactions, such as heavy overhead equipment falling on sensitive equipment below, the effect of leaks and electrical problems on nearby equipment, and difficulties of inspection and maintenance. The reviewer will seek evidence that the need for design bases reconstitution was investigated, that reconstitution was accomplished as necessary, and that new or revised documentation was properly incorporated into the CM function. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.

11.5.2.3 Maintenance

If the applicant's submittal is acceptable, the reviewer conducts the review of the applicant's maintenance function with respect to the acceptance criteria. The reviewer will evaluate the applicant's description of how the maintenance function will coordinate and utilize the other management measures listed in this chapter. The Primary Reviewer should consult with the Supporting Reviewers to identify any common weaknesses in the applicant's approach and consider these during the review.

An acceptable maintenance function includes descriptions and demonstrates applicant's adequate commitments to the following: corrective maintenance, preventive maintenance, surveillance/monitoring, and functional testing. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.

11.5.2.4 Training and Qualification

After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the primary reviewer should perform a safety evaluation against the acceptance criteria described in Section 11.4, recognizing that the rigor and formality of a systematic approach to training and the required personnel qualification may be graded to correspond to the hazard potential of the facility and to the complexity of the training needed. The review should determine whether the applicant has adequately planned for the training and personnel qualification to be accomplished and whether necessary policies, procedures, and instructions will be in place and appropriate training and qualification will be accomplished before personnel begin activities relied on for safety. The reviewers should focus on the training and qualification of personnel who will perform activities relied on for safety.

The secondary reviewer should confirm that the applicant's personnel training and qualification commitments are consistent with other sections of the submittal. The secondary reviewer

should also integrate the personnel training and qualification input into the Safety Evaluation Report (SER).

The supporting reviewer should become familiar with the applicant's personnel training and qualification commitments and determine whether ongoing activities are in agreement with them.
On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP. The staff or applicant may also propose license conditions to ensure that the personnel training and qualification meet the acceptance criteria. The review should result in a determination that there is reasonable assurance that the applicant's personnel training and qualification will ensure that only properly trained and qualified personnel will perform activities relied on for safety.

When the safety evaluation is complete, the primary staff reviewer, with assistance from the other reviewers, should prepare the personnel training and qualification input for the SER as described in Section 11.6 using the acceptance criteria from Section 11.4.

11.5.2.5 Procedures

Upon acceptance of the application for review, the primary reviewer will evaluate whether the applicant has adequately addressed the acceptance criteria listed in section 11.4. The reviewer will document in a safety evaluation report that the applicant has committed to the following:

1. Controls identified in the ISA summary are highlighted in safety procedures (i.e., procedures that constitute administrative controls for safety). There may be several levels of requirements within procedures for diagnosing and correcting process upsets, dealing with abnormal situations, or other matters. There is a clear hierarchy of requirements within procedures. Cautions and notes appearing in procedures precede the steps to which they apply. Rules for entering and leaving a procedure are clear.

2. Procedures important to safety are independently verified and validated before use and this is documented in a policy on procedures.

3. Policy and administrative procedures, non-crucial operating procedures, and other non-operational procedures that do not impact items relied on for safety or other environmental, safety, and health concerns need not be controlled with the stringency applied to operating procedures or management control procedures associated with controls specified by the ISA summary. The applicability of less stringent procedure control should be specified to avoid misunderstandings in implementation.

4. Changes to operating, management control, or maintenance procedures are reviewed and approved by an independent multi-disciplinary safety review team and controlled by the configuration management function.

5. The applicant includes a statement to follow approved procedures while processing licensed special nuclear material.

6. Procedures exist for the notification of operations personnel before and after maintenance is performed on items relied on for safety and activities are controlled by procedures.

On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this SRP.

11.5.2.6 Audits and Assessments

After determining that the application is acceptable for review in accordance with Section 11.5.1, above, the primary reviewer will perform a safety evaluation against the acceptance criteria described in Section 11.4. The review should determine whether the applicant has adequately planned for audits and assessments to be accomplished and whether necessary policies, personnel, procedures, and instructions will be in place to begin audits and assessments early; that is, during the design of items relied on for safety.

If the applicant references other sections of the application when describing its audits and assessments, the primary reviewer should review these other sections of the application to determine the applicant's commitment to overall audits and assessments and the proposed method for implementation. The reviewers should focus on audits and assessments of items relied upon for safety.

The secondary reviewer should confirm that the applicant's audit and assessment commitments are consistent with other sections of the submittal. The secondary reviewer is also responsible for integrating the audit and assessment input into the Safety Evaluation Report (SER).

The supporting reviewer should become familiar with the applicant's audit and assessment commitments and determine whether ongoing audits and assessments of the applicant and the applicant's principal contractors are in agreement with them.

On the basis of its review, the staff may request that the applicant provide additional information or modify the application to meet the acceptance criteria in SRP Subsection 11.7.4. The staff or applicant may also propose license conditions to ensure audits and assessments meet the acceptance criteria. The review should result in a determination that there is reasonable assurance that the audits and assessments of the applicant and the applicant's principal contractors will provide additional assurance that items relied on for safety will perform satisfactorily in service and that activities relied on for safety will be performed satisfactorily.

The final step in the review is the primary reviewer's writing of a Safety Evaluation Report (SER) input that summarizes the conduct of the review, identifies what material in the application forms the basis for a finding of reasonable assurance with respect to the regulatory requirements, and presents any recommendations for license conditions that are necessary to conclude that reasonable assurance is achieved.

On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 11.4 of this section.

11.5.2.7 Incident Investigations

The primary reviewer will verify that the applicant has described a comprehensive incident investigation function based on the areas of review in Section 11.3 and the acceptance criteria presented in Section 11.4 of this SRP.

During the review, the reviewer will consult with the NRC inspection staff and review any historical information regarding the adequacy of the applicant's incident investigation process. On the basis of its review, the staff may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria in Section 3.7.4 of this SRP.

11.5.2.8 Records Management

The reviewer will review the applicant's records management system to determine the adequacy of the policies, procedures, and practices. The reviewer should coordinate this review with the person reviewing the CM function.

For fuel cycle facilities that are parts of larger organizations, certain documents may be retained or stored at a site other than the plant site. For example, master drawings for structures might be kept in the engineering department of the headquarters of the parent company. The reviewer may choose to review the physical characteristics of these offsite record storage areas, as well, particularly for records for controls or high risk accidents sequences.

On the basis of the review, the reviewer may request that the applicant provide additional information or modify the submittal to meet the acceptance criteria presented in Section 11.4 of this SRP.

11.6 EVALUATION FINDINGS

The staff's evaluation should verify that the license application provides sufficient information to satisfy the regulatory requirements of Section 11.4.1 and that the regulatory acceptance criteria in Section 11.4.3 have been appropriately considered in satisfying the requirements. On the basis of this information, the staff should conclude that this evaluation is complete. The reviewers should write material suitable for inclusion in the SER prepared for the entire application. The SER should include a summary statement of what was evaluated and the basis for the reviewers' conclusions.

The staff can document the evaluation as follows:

11.6.1 Quality Assurance

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable. The review record should demonstrate that the adequacy of the applicant's QA program, as applied to items relied on for safety, for design, construction, operations] *the NRC staff has concluded that the applicant has*

adequately described its QA program (and the QA program of its principal contractors). The staff concludes further that:

1. The applicant has established and documented a commitment for an organization responsible for developing, implementing, and assessing the management controls for ensuring safe facility operations in accordance with the criteria in Section 11.4 of this SRP.

2. The applicant has established and documented a commitment for QA, and the administrative controls for staffing, performance, assessing findings, and implementing corrective actions are in place.

3. The applicant has developed a process for preparation and control of written administrative plant procedures, including procedures for evaluating changes to procedures, items, tests, and processes relied on for safety. A process for review, approval, and documentation of procedures will be implemented and maintained.

4. The applicant has established and documented a surveillance, test, and inspection program to ensure satisfactory in-service performance of items relied on for safety. Specified standards or criteria and testing steps have been provided.

5. Periodic independent audits are conducted to determine the effectiveness of the management controls. Management controls will provide for documentation of audit findings and implementation of corrective actions.

6. Training requirements have been established and documented to provide employees with the skills to perform their jobs safely. Management controls have been provided for evaluation of the effectiveness of training against predetermined objectives and criteria.

7. The organizations and persons performing QA functions have the required independence and authority to effectively carry out their QA functions without undue influence from those directly responsible for process operations.

8. QA covers the items relied on for safety, as identified in the ISA summary, and controls are established to prevent hazards from becoming pathways to higher risks and accidents.

Accordingly, the staff concludes that the applicant's QA program (and the QA program of its principal contractors) meets the requirements of 10 CFR Part 70 and provide reasonable assurance of protection of public health and safety and of the environment.

11.6.2 Configuration Management

The staff has reviewed the Configuration Management (CM) function for (name of facility) according to Section 11of the Standard Review Plan. [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.]

The applicant has suitably and acceptably described its commitment to a proposed CM system, including the method for managing changes in procedures, facilities, activities, and equipment for systems important to safety. Management level policies and procedures,

including an analysis and independent safety review of any proposed activity involving systems important to safety, are described that will ensure that the relationship between design requirements, physical configuration, and facility documentation is maintained as part of a new activity or change in an existing activity involving licensed material. The management measures will include (or do include) the following elements of CM.

1. CM Management

The organizational structure, procedures, and responsibilities necessary to implement configuration management are in place or committed to.

2. Design Requirements

The design requirements and bases are documented and supported by analyses and the documentation is maintained current.

3. Document Control

Documents, including drawings, are appropriately stored and accessible. Drawings and related documents adequately describe systems important to safety.

4. Change Control

Responsibilities and procedures adequately describe how the applicant will achieve and maintain strict consistency among the design requirements, the physical configuration, and the facility documentation. Methods are in place for suitable analysis, review, approval, and implementation of identified changes to systems important to safety. This includes appropriate CM controls to assure configuration verification, functional tests, and accurate documentation for equipment or procedures that have been modified.

11.6.3 Maintenance

The applicant has committed to maintenance of items relied on for safety. The applicant's maintenance commitments contain the basic elements to ensure availability and reliability: corrective maintenance, preventive maintenance, functional testing, equipment calibration, work control, and management measures for items relied on for safety. The applicant's maintenance function is proactive, using maintenance records, preventive maintenance records, and surveillance tests to analyze equipment performance and to seek the root causes of repetitive failures.

The surveillance activities described in this section of the application ensure the validity of the ISA by examination and calibration and testing of equipment that monitors process safety parameters and acts to prevent or mitigate accident consequences.

The maintenance function: (1) is based on approved procedures; (2) employs work control methods that properly consider personnel safety, awareness of facility operating groups, quality assurance, and the rules of configuration management; (3) links items relied on for

safety requiring maintenance to the ISA summary; (4) justifies the preventive maintenance intervals in the terms of equipment reliability goals; (5) provides for training that emphasizes importance of ISA or ISA summary identified controls, regulations, codes, and personal safety; and (6) creates documentation that includes detailed records of all surveillance, inspections, equipment failures, repairs, and replacements.

The staff concludes that the applicant's maintenance functions meet the requirements of 10 CFR Part 70, and provide reasonable assurance that the health and safety of the public are protected.

In cases where the SER is drafted in advance of resolving all outstanding maintenance issues, the reviewer documents the review as described above and includes a list of open issues that require resolution prior to the staff's position finding of reasonable assurance.
For partial reviews, revisions, and process changes, the reviewer will use applicable sections of the acceptance criteria and the SER will be written to reflect what portions were not reviewed and the maintenance significance, if any. Upon completion of the review, NRC staff may impose temporary or one-time license conditions to authorize short duration activities. For certain functions and requirements that concern safety or regulatory issues, a license condition may be imposed and remain in effect until removed by an amendment or license renewal.

11.6.4 Training and Qualification

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] *the NRC staff has concluded that the applicant has adequately described and assessed its personnel training and qualification that (1) satisfy regulatory requirements, (2) are consistent with the guidance in this SRP, and (3) are acceptable.*

There is reasonable assurance that implementation of the described training and qualification will result in personnel who are qualified and competent to design, construct, start-up, operate, maintain, modify, and decommission the facility safely. The staff concludes that the applicant's plan for personnel training and qualification meet the requirements of 10 CFR Part 70.

11.6.5 Procedures

The application has described suitably detailed process for the development, approval, and implementation of procedures. Special attention has been paid to items relied on for safety, as well as to systems important to the health of plant workers and the public and to the protection of the environment.

11.6.6 Audits and Assessments

Based on its review of the license application, [Insert a summary statement of what was evaluated and why the reviewer finds the submittal acceptable.] *the NRC staff has concluded that the applicant has adequately described its audits and assessments. The staff has reviewed the applicant's plan for audits and assessments and finds them acceptable.*

The staff concludes that the applicant's plan for audits and assessments meets the requirements of 10 CFR Part 70 and provides reasonable assurance of protection of (1) the health and safety of the public and workers and (2) the environment.

11.6.7 Incident Investigations

The applicant has committed to and established an organization responsible for performing incident investigations of abnormal events that may occur during operation of the facility, determining the root cause(s) of the event, and recommending corrective actions for ensuring a safe facility and safe facility operations in accordance with the acceptance criteria of Subsection 11.4 of the SRP.

The applicant has committed to monitoring and documenting of corrective actions, through completion.

The applicant has committed to the maintenance of documentation so that "lessons learned" may be applied to future operations of the facility.

Accordingly, the staff concludes that the applicant's description of the incident investigation process complies with applicable NRC regulations and is adequate.

11.6.8 Records Management

The staff has reviewed the applicant's records management system against the SRP's acceptance criteria and concluded that the system: (1) will be effective in collecting, verifying, protecting, and storing information about the health and safety (H&S) aspects of the facility and its operations and will be able to retrieve the information in readable form for the designated lifetimes of the records; (2) will provide a records storage area(s) with the capability to protect and preserve H&S records that are stored there during the mandated periods, including protection of the stored records against loss, theft, tampering or damage during and after emergencies; and (3) will ensure that any deficiencies in the H&S records management system or its implementation will be detected and corrected in a timely manner.

11.7 REFERENCES

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DOE,“Implementation Guide for use with 10 CFR Part 830.120 and DOE Order 5700.6C,” September 1997 draft.

Appendix A: CHECKLIST FOR PROCEDURES

All activities listed below are covered by written procedures. The list is not intended to be all inclusive nor is it intended to imply that procedures be developed with the same titles as those on the list. This listing is divided into four categories and provides guidance on topics to be covered.

1. Management Control Procedures:

   Training
   Audits and Assessments
   Incident Investigation
   Records Management
   Configuration Management
   Quality Assurance
   Equipment control (lockout/tagout)
   Shift turnover
   Work Control
   Management control
   Procedure management
   Nuclear criticality safety
   Fire protection
   Radiation protection
   Radioactive waste management
   Maintenance
   Environmental protection
   Chemical process safety
   Operations
   Calibration control
   Preventive maintenance

2. Operating Procedures

   a. System Procedures that Address Startup, Operation, Shutdown Control of Process Operations and Recovery After a Process Upset

      Ventilation
      Criticality alarms
      Shift routines, shift turnover and operating practices
      Decontamination operations
      Uranium recovery
      Plant Utilities (air, other gases, cooling water, fire water, steam)
      Temporary changes in operating procedures

   b. Abnormal Operation/Alarm Response:

Loss of cooling water
Loss of instrument air
Loss of electrical power
Loss of criticality alarm system
Fires
Chemical process releases

3. Maintenance Activities that Address System Repair, Calibration, Surveillance, and Functional Testing

Repairs and preventive repairs of items relied on for safety
Testing of criticality alarm units
Calibration of items relied on for safety
HEPA filter maintenance
Functional testing of items relied on for safety
Relief valve replacement/testing
Surveillance/monitoring
Pressure vessel testing
Non-fired pressure vessel testing
Piping integrity testing
Containment device testing

4. Emergency Procedures:

Response to a criticality
Hazardous process chemical releases (including UF_6)

APPENDIX B: RECORDS

The requirements for records management vary according to the nature of the facility and the hazards and risks posed by it. Examples of the records required by 10 CFR Parts 19, 20, 21, 25, and 70 are presented below. These listings are organized under the chapter headings of the SRP. Although they indicate the kinds of records to be found in these chapters of the SRP, the listing is not intended to be exhaustive or prescriptive in format. For example, in particular instances, different or additional records might fall within these groupings. Furthermore, the applicant may choose to organize the records in ways other than shown here.

Examples of Records

SRP Chapter

1.0 General Information

Construction records

Facility and equipment descriptions and drawings

Design criteria, requirements, and bases for structures, systems, or components, relied on for safety as specified by the facility configuration management system

Records of facility changes and associated integrated safety analyses, as specified by the facility configuration management system

Safety analyses, reports, and assessments

Records of site characterization measurements and data

Records pertaining to onsite disposal of radioactive or mixed wastes in surface landfills

Procurement records, including specifications for items relied on for safety

2.0 Organization and Administration

Administrative procedures with safety implications

Change control records for material control and accounting program

Organization charts, position descriptions, and qualifications records

Safety and health compliance records, medical records, personnel exposure records, etc.

Quality Assurance records

2.0 Organization and Administration (continued)

Safety inspections, audits, assessments, and investigations

Safety Statistics and trends

3.0 Integrated Safety Analysis

4.0 Radiation Safety

Bioassay data

Exposure records

Radiation protection (and contamination control) records

Radiation training records

Radiation work permits

5.0 Nuclear Criticality Safety

Nuclear criticality control written procedures and statistics

Nuclear criticality safety analyses

Records pertaining to nuclear criticality inspections, audits, investigations, and assessments

Records pertaining to nuclear criticality incidents, unusual occurrences, or accidents

Records pertaining to nuclear criticality safety analyses

6.0 Chemical Safety

Chemical process safety procedures and plans

Records pertaining to chemical process inspections, audits, investigations, and assessments

Diagrams, charts, and drawings

Records pertaining to chemical process incidents, unusual occurrences, or accidents

Chemical process safety reports and analyses

Chemical process safety training

7.0 Fire Safety

Fire Hazard Analysis

Fire prevention measures, including hot-work permits and fire-watch records

Records pertaining to inspection, maintenance, and testing of fire protection equipment

Records pertaining to fire protection training and retraining of response teams

Pre-fire emergency plans

8.0 Emergency Management

Emergency plan(s) and procedures

Comments on emergency plan from outside emergency response organizations

Emergency drill records

Memorandum of understanding with outside emergency response organizations

Records of actual events

Records pertaining to the training and retraining of personnel involved in emergency preparedness functions

Records pertaining to the inspection and maintenance of emergency response equipment and supplies

9.0 Environmental Protection

Environmental release and monitoring records

Environmental Report and Supplements to the Environmental Report, as applicable

10. 0 Decommissioning

Decommissioning records

Financial assurance documents

Decommissioning cost estimates

Site characterization data

Final survey data

Decommissioning procedures

11.0 Management Control Systems

11.1 Quality Assurance

- audit and assessment records
- inspection records
- test records
- corrective action records

11.2 Configuration Management

- safety analyses, reports, and assessments that support the physical configuration of process designs, and changes to those designs
- validation records for computer software used for safety analysis or MC&A
- ISA documents, including process descriptions, plant drawings and specifications, purchase specifications for items relied on for safety
- approved, current operating procedures and emergency operating procedures

11.3 Maintenance

- failure log (required by 70.62)
- preventive maintenance records, including trending and root cause analysis
- calibration and testing data for items relied on for safety
- corrective maintenance records

11.4 Training and Qualification

- personnel training and qualification records
- procedures

11.5 Procedures

- standard operating procedures
- functional test procedures

11.6 Audits and Assessments

- audits and assessments of safety and environmental activities

11.7 Incident Investigations

- investigation reports
- changes recommended by investigation reports, how and when implemented
- summary of reportable events for the term of the license
- incident investigation policy

11.8 Records Management

- policy
- material storage records
- records of receipt, transfer and disposal of radioactive material